Brazilian Homeopathic Pharmacopoeia

3rd edition

Esta tradução é um produto de termo de cooperação entre a Agência Nacional de Vigilância Sanitária (ANVISA) e a Organização Pan-Americana de Saúde (OPAS), e não substitui a versão em português.

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2011

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SUMÁRIO

1. PREFACE 5
2. HISTORY 7
3. BRAZILIAN PHARMACOPOEIA 9
4. PURPOSES 15
5. GENERAL DETERMINATIONS 17
   5.1 Concepts and definitions 17
   5.2 Nomenclature, abbreviated names, abbreviations and symbols, synonymy 18
6. HOMEOPATHIC MEDICINES 23
   6.1 Origin 23
   6.2 List of the most used homeopathic medicines 23
7. INERT INPUTS AND PACKAGES 37
   7.1 Excipients and vehicles 37
   7.2 Packaging material 37
8. GENERAL PROCEDURES 39
   8.1 Drugs of vegetable origin 39
   8.2 Drugs of animal origin 39
   8.3 Drugs of mineral origin 39
   8.4 Drugs of chemical-pharmaceutical origin 40
   8.5 Drugs of other origins, biological, pathological or not 40
   8.6 Drugs of other nature 40
   8.7 Inert inputs 40
   8.8 Alcoholic Solutions 40
   8.9 Glycerine-Based Dilutions 40
9. ANALYSIS AND TESTING METHODS 41
   9.1 Physical And Physical-Chemical Determinations 41
   9.2 Chemical determinations 46
   9.3 Analysis methods of vegetable drugs 49
   9.4 Biological methods 50
10. METHOD OF PREPARATION OF THE MOTHER TINCTURE 51
   10.1 Preparation of the mother tincture of vegetable origin 51
   10.2 Preparation of the mother tincture of animal origin 53
11. PREPARATION METHODS OF THE DERIVATIVE PHARMACEUTICAL FORMS 55
   11.1 Hahnemann's method 55
   11.2 Korsakov's method 58
   11.3 Continuous flow method 58
12. PREPARATION METHODS OF THE PHARMACEUTICAL FORMS FOR DISPENSING 61
   12.1 Pharmaceutical forms for internal use 61
   12.2 Pharmaceutical forms for external use 72
13. BIOTHERAPEUTICS AND ISOTHERAPEUTICS 81
   13.1 Classification 81
   13.2 Minimum requirements for the preparation of biotherapeutics and isotherapeutics 81
14. LABELLING 85

This translation does not replace the portuguese version.

15. MONOGRAFIAS 87
16. REAGENTS 273
16.1 Reagents and reagent solutions 273
16.2 Volumetric solution 276
16.3 Buffer 276
ATTACHMENT A – MESH AND TAMISES' OPENING EQUIVALENCE 277
ATTACHMENT B - CONVERTION FROM NORMALITY TO MOLARITY 279
ATTACHMENT C - ALCOHOLOMETRY 281

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1. PREFACE

With two hundred years of age, the homeophatic science has been marking its place as an outstanding alternative in the human therapeutics, with strong insertion in the animal therapeutics.

Hahnemann, in 1799, used the belladonna in the control of a scarlat fever epidemics, treated afterwards a Typhus epidemics, achieving about 99% of success in the results.

History further described several cases which led reputed researchers of the healthcare area to search in this alternative for the art of healing by introducing the science in the routine of the medicine and pharmacy courses, being a reality in the public healthcare services nowadays.

The contents of the Pharmacopoeias and Forms aim at guiding the medicine manufacturing and the regulation of the pharmaceutical sectors involved in the manufacturing and control of drugs, inputs and pharmaceutical specialties.

Brazilian Health Surveillance Agency, by means of the Brazilian Pharmacopoeia Commission, relied on the Thematic Technical Committee "***HOMEOPATHY***" the task of making available the updated and most complete version of the compendium, based on internationally disclosed knowledge, adapted to the proposal of the fifth edition of the Brazilian Pharmacopoeia.

The Committee was guided to approach Brazilian associations involved with the subject, because the dialogue and experience accumulated in decades of good services that this pharmaceutical segment provides to the Nation are very significant.

The work of the Committee was complemented by the harmonization process towards the uniformity in prescribing and preparing the homeopathic medicines, it is a work thoroughly executed by the members of the Thematic Technical Committee "***NORMALIZATION OF NOMENCLATURE AND TEXTS***".

The public acknowledgment of this significant area of the pharmaceutical activity enhances the Brazilian diversity towards feasible alternatives ensuring Brazilian citizens with the best life quality and freedom to look after the best for themselves.

This work, once it is made public, may be increasingly improved, extended, complemented by the participation of the professionals who use it.

The Brazilian Pharmacopoeia Commission expects to have, in each of the users of this compendium, along with the potential in the maintenance of the works that are also the differential in the culture, science and technology of a constantly growing country.

Dr. Gerson Antônio Pianetti
President of the Brazilian Pharmacopoeia Commission

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2. HISTORY

Homeopathic Science is born in 1976, after the publication of a scientific article with the following title: "Ensaio para descobrir as virtudes curativas das substâncias medicinais, seguido de alguns comentários sobre os princípios curativos admitidos até nossos dias". The author of this article was the German doctor Cristiano Frederico Samuel Hahnemann, creator of the homeopathic therapeutics. Hahnemann was born in Eastern Germany, in the city of Meissen, in 1755. A personality highlighted by a sharp intelligence and extremally critical scientific spirit motivated him from a young age the study of medicine and chemistry. Considering that the sciences and medicine teaching processes at that time (1755) was very theoretical and exempt of any contact with the patient, medical practice involved a knowldge more philosophical than practical. It was the medicine of sangrias and purgatives that mostly made the clinical condition of the patients worse instead of healing them. Hahnemann practiced this medicine for eight years, dividing his time with the general medicine, the study of medicine and chemistry. We cannot leave out Hahnemann's involvement with scientific translations, a result of his brilliant intelligence, which made him a polyglot at the 24 years of age, dominating nine languages (Latin, Greek, Hebrew, English, French, Italian, Spanish, Arabian and German). Before developing homeopathy, Hahnemann already had an impressive productivity, publishing a total of eight works, among scientific translations and original literary works, in a short period of three years (1786 - 1788) in which he stood himself against the use of lead plasters or internal corrosive sublimate, which toxicity he denounced. He published the criteria of medicine purity and falsification. He described in the influence of some gases in the wine fermentation. He criticized the abusive use of alcohol and coffee, accusing them of two enemies of the nervous system and highlighted the significance of the hygienization to prevent diseases, among other works.

In 1790, at the request of one of this editors from Leipzig, Hahnemann translated the Treatise on Medical Matters, in two volumes, written by the Scottish doctor William Cullem, considered an international authority in the composition and activity of medicinal drugs. Upon translating the article assigned to the antimalarial drug *Cinchona officinalis* (quinine), Hahnemann amazes himself with Cullen's statement: "Quinine heals malaria by strengthening the stomach, due to its bitter and astringent properties". Hahnemann resolved to try on himself the use of the famous quinine powder, taking it for several days, twice a day, four drachmas (equivalent to about 17 g) of the drug. During this experiment, he recorded all of the symptoms developed by using quinine, such as: intermitent fever, weakness, sleepiness, shivers and other symptoms commonly associated with malaria. He concluded that quinine may be used because it was capable of producing similar symptoms as the disease, when it was used by a healthy individual. Thus, Hahnemann rescued the Hippocratic Law of Similarity: "Similia similibus curantur" and stated: "Medicines may only heal similar diseases to those that they may produce themselves". This is the original reflection that, along with the medicine experiments in health and sensitive people, allowed the creation of the homeopathy, in 1796. The therapeutics is, therefore, based in solid structures involving the "Law of Similarity", "Experiments in Healthy Men", "Use of Minimum or Infinitesimal Doses", "Use of a Single Medicine". Hahnemann tested on himself and his students about 60 different substances, cataloging the set of physical and subjective signals and symptoms (pathogenesis) that the non-sick individuals developed during the experiment and highlighted the significance of this experiment to be made with one substance at a time. Dilution and dynamization are concepts introduced by Hahnemann, aiming at the reduction of the substance toxicity (dilution) and the release of the latent medicative power of

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the substances (dynamization). Hahnemann's studies were performed until his death, at the 88 years of age, when he was very reputed and prestiged. During the development of Hahnemann's homeopathy he published, among others, three major works: Organon of Rational Medicine (1810); Materia Medica Pura (1811) and Volume of Chronical Diseases (1828).

Homeopathy came to Brazil in 1840, brought by the French doctor, Dr. Benoit Jules Mure. At that time, Brazil had no autonomy to manufacture medicines, then, the homeopathic raw materials (tinctures, minerals, vegetables) were imported, particularly from Europe. The current scenario is very different and homeopathy is diffused in several countries around the world. In Brazil, the preparation of homeopathic medicines is supported by the Brazilian Homeopathic Pharmacopoeia, which had its first edition published in 1977. Homeopathic Science continues on a straightfoward development, with scientific works being performed with different models, such as: laboratory animals, cell cultures, physical-chemical models, among others. Clinical, double-blind, randomized, controlled placebo tests were and are performed in several parts around the world, towards the scientific consolidation of the homeopathy. Scientists around the world are developing protocols aiming at the understanding of the dilluted and dynamized substanced used for this therapeutics, which values not only the disease, but also the sick patient, with their susceptibility, fragility, genetic heritage and emotional inconsistencies.

Therefore, Homeopathy is a science which meets, since 1790, the scientific criteria originally established by Hahnemann, which has been proved by the scientific works published over the last decade.

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4. PURPOSES

Brazilian Pharmacopoeia Commission approves the Brazilian Homeopathic Pharmacopoeia 3rd edition (FHB 3) for the following applications:

1. Drugstores and industrial pharmaceutical laboratories preparing homeopathic inputs and homeopathic medicines.
2. Licensed prescribers in the preparation of the homeopathic prescriptions.
3. Agencies responsible for the inspection, aiming at ensuring the good practices of manipulation and dispensing at the drugstores, manufacturing and control at the industrial laboratories and prescription concerning the homeopathic clinics.
4. Homeopathic pharmacotechnical teaching process in undergraduate and graduate health courses.

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5. GENERAL DETERMINATIONS

5.1 CONCEPTS AND DEFINITIONS

TITLE

The complete title of this work is "Homeopathic Pharmacopoeia of the Federative Republic of Brazil, 3rd edition". It may be named as "Brazilian Homeopathic Pharmacopoeia, 3rd edition" or "FHB 3".

DEFINITIONS

Dilution
It is the reduction of the active input concentration by adding the proper inert input.

Dynamization
It is the process of dilutions followed by succussions and successive triturations of the active input into proper inert input.

Drug
Raw material of mineral, vegetal, animal or biological origin, used for the preparation of the homeopathic medicine.

Scale
It is the proportion between the active input and the inert input deployed in the preparatoin of different dynamizations. The derivative pharmaceutical forms are prepared pursuant to *Centesimal, Decimal and Fifty milesimal scales:*

- *Centesimal Scale:* prepared in the proportion of 1/100 (one part of the active input into 99 parts of the inert input, amounting a total of 100 parts);
- *Decimal Scale:* prepared in the proportion of 1/10 (one part of the active input into nine parts of the inert input, amounting a total of 10 parts);
- *Fifty Milesimal Scale:* prepared in the proportion of 1/50,000.

Pharmaceuticals
Active input with therapeutical purpose that, in contact or when introduced into a biological system, modifies one or more of its functions.

Derivative pharmaceutical forms
They are preparations arisen out of the active input obtained by dilutions in proper inert inputs followed by succussions and/or successive tritutations, pursuant to the homeopathic pharmacothecnical.

Active input
It is the starting point for the preparation of the homeopathic medicine, constituted of drug, pharmaceuticals, mother tincture or derivative pharmaceutical form.

Inert Input

Substance used as a vehicle or excipient for the preparation of the homeopathic medicines.

Matrix
Stock active input for the preparation of homeopathic medicines or derivative pharmaceutical forms.

Homeopathic medicine
It is every pharmaceutical form of dispensing administered in accordance with the similarity and/or indentity principle, with curative and/or preventive purpose. It is obtained through the dynamization technique and it is for internal or external use.

Compound homeopathic medicine
It is prepared from two or more active inputs.

Single component homeopathic medicine
It is prepared from a single active input.

Potency
It is the quantitative indication of the number of dynamizations that a matrix or homeopathic medicine received.

Succussion
Manual process consisting in the vigorous and rhythmic movement of the forearm against a semirigid bulkhead of the active input, dissolved into proper inert input. It may also be performed in the automated form, since it simulates the manual process.

Mother tincture
It is a liquid preparation resulting from the proper extracting liquid action over certain drug of animal or vegetable origin.

Trituration
It consists of the active input reduction to smaller particles by means of automated or manual process, using lactose as inert input, aiming at its dynamization.

5.2 NOMENCLATURE, ABBREVIATED NAMES, ABBREVIATIONS AND SYMBOLS, SYNONYMY

NOMENCLATURE
For the designation of the homeopathic medicines, *Scientific Names* may be used, in accordance with the rules of the internal codes for botanical, zoological, biological, chemical and pharmaceutical nomenclature, as well as *Homeopathic Names* consecrated by the use (appearing in Pharmacopoeias, Medical Articles, Reports or scientific works acknowledged by the homeopathy).

In the botanical, zoological and biological nomenclature, the gender is written with the first letter in upper case and the species in lower case.

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Examples.
- *Apis mellifica*.
- *Bryonia alba*.
- *Chelidonium majus*.
- *Conium maculatum*.
- *Digitalis purpurea*.
- *Lycopodium clavatum*.

Regarding the medicines with names homeopathically consecrated by their use, using only the name of the species, omitting the name of the gender, is authorized.

Examples.
- *Belladona*, instead of *Atropa belladona*.
- *Colocynthis*, instead of *Citrullus colocynthis*.
- *Dulcamara*, instead of *Solanum dulcamara*.
- *Millefolium*, instead of *Achillea millefolium*.
- *Nux vomica*, instead of *Strychnos nux vomica*.

Regarding littled used species, their full name must be quoted.

Examples.
- *Aconitum ferox*, in order to distinguish it from *Aconitum napellus*.
- *Clematis erecta*, in order to distinguish it from *Clematis vitalba*.
- *Crotalus horridus*, in order to distinguish it from *Crotalus terrificus*.
- *Dioscorea petrea*, in order to distinguish it from *Dioscorea villosa*.
- *Eupatorium purpureum*, in order to distinguish it from *Eupatorium perfoliatum*.
- *Lobelia inflata*, in order to distinguish it from *Lobelia purpurea*.

Regarding the designation of medicines of chemical origin, the designations consecrated by use in homeopathy are allowed, in addition to the official scientific name.

Examples.
- *Barium* and its composites - *Baryta* and its composites.
- *Bromum* and its composites - *Bromium* and its composites.
- *Calcium* and its composites - *Calcarea* and its composites.
- Kalium and its composites - Kali and its composites.
- *Iodum* and its composites - *Iodium* and its composites.
- *Magnesium* and its composites - *Magnesia* and its composites.
- *Natrium* and its composites - *Natrum* and its composites.
- *Sulfur* and its composites - *Sulphur* and its composites.

Regarding chemical medicines, acids and salts, organic or inorganic in nature, the designation consecrated by homeopathy is allowed, in addition to the official chemical designation, being written, preferably, at first, the name of the elment of the positive valence ion and, in the second place, the negative valence ion.

Examples.
- *Acidum aceticum* or *Acetic acidum*.

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- *Acidum benzoicum* or *Benzoic acidum*.
- *Acidum muriaticum* or *Muriatis acidum*.
- *Acidum lacticum* or *Lactis acidum*.
- *Acidum nitricum* or *Nitri acidum*.
- *Acidum sulfuricum* or *Sulphuris acidum*.

ABBREVIATED NAMES

The usage of abbreviated names of the medicine may make the prescription understanding difficult. The use of arbitrary abbreviations is forbidden by the Brazilian pharmaceutical legislation.

Examples of notations that may generate confusion.

Arsenic. sulf.
- *Arsenicum sulfuratum flavum* = Arsenic. sulf. flav = Arsenic sulfide = As2S3
- *Arsenicum sulfuratum rubrum* = Arsenic. sulf. rub. = Arsenic disulfide = As2S2

Aur. chlor.
- *Aurum chloratum* = Aur. chlorat. = AuHCl4-4H2O
- *Aurum chloratum natronatum* = Aur. chlorat. natron. = NaAuHCl4-2H2O

Kali chlor.
- *Kalium chloratum* = Kali chloratil = Potassium chlorate = KClO3
- *Kalium chloricum* = Kali chloric. = Potassium chloride = KCl

Antim. ars.
- *Antimonium arsenicosum* = Antim. arsenic. = Sb2O5-As2O3
- *Antimonium arsenicum* = Antim. arsenicum = Sb3-AsO3

Examples of correct notations.
- *Aconitum napellus* ou *Aconitum* - Acon. or Aconit.
- *Atropa belladona* ou *Belladona* - Bell. or Bellad.
- *Mercurius solubilis* - Merc. sol. or Mercur. sol.
- *Mercurius sublimatus corrosivus* - Merc. corr.
- *Solanum dulcamara* or *Dulcamara* - Dulc. or Dulcam.

ABBREVIATIONS AND SYMBOLS
- Tablet = tab. Dilution = dil.
- Dynamization = dyn.
- Centesimal scale prepared in accordance with the Hahnemann's method = CH
- Fifity milesimal scale = LM
- Hering's decimal scale prepared in accordance with the Hahnemann's method = DH
- Brazilian Pharmacopoeia = FB
- Brazilian Homeopathic Pharmacopoeia = FHB
- Basic pharmaceutical form, Mother tincture = Mother tinct., TM, Globule = glob.
- Continuous flow method = FC Korsakov's Method = K Microglobule = mcglob.
- Equal parts = ana = ãã Pastille = past. Sufficient quantity = qs

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- Sufficient quantity for = qsp Dry residue in mother tincture = r.s.
- Solid residue of fresh vegetable = r.sol. Solution = sol.
- Bar = bar.
- Alcoholic title of the mother tincture = tit.alc.
- Trituration = trit.

SYNONYMY
The use of symbols must be restricted to those appearing in the works consecrated in the scientific literature.

Examples.
- *Apisinum = Apis virus*.
- *Arsenicum album = Metallum album*.
- *Blatta orientalis = Periplaneta orientalis*.
- *Bryonia alba = Vitis alba*.
- *Calcarea carbonica = Calcarea ostrearum, Calcarea osthreica*.
- *Chamomilla = Matricaria*.
- *Glonoinum = Trinitrinum*.
- *Graphites = Carbo mineralis*.
- *Hydrastis canadensis = Warneria canadensis*.
- *Ipeca ou Radix = Cephaelis ipecacuanha*.
- *Lycopodium = Muscus clavatus*.
- *Mercurius sulf. ruber = Cinnabaris*.
- *Nux vomica = Colubrina*.
- *Pulsatilla = Anemone pratensis*.
- *Rus toxicocodendron = Vitis canadensis*.
- *Secale cornutum = Claviceps purpurea*.
- *Sterculla acuminata = Kola, Cola*.
- *Sulphur = Flavum depuratum*.
- *Thuya occidentalis = Arbor vitae*.

Medicines presented with arbitrary synonym denomination which are not appearing in the works previously quoted, as well as the use of code, acronym, number and/or arbitrary name are not allowed.

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6. HOMEOPATHIC MEDICINES

6.1 ORIGIN

Medicines used in homeopathy have origin in different nature kingdoms, as well as in chemical-pharmaceutical products, substances and/or biological or pathological materials or not, in addition to other agents of different nature.

The Vegetable Kingdom constitutes the biggest source for preparation of homeopathic medicines. The vegetable may be used as a whole and/or in parts, in several vegetative phases, such as: supraterrenal, head, leaf, flower, hair, peel, log, rhizome, fruit and seed. Extractive or transformation products are also used: juice, resine, essence, etc. The used part, the vegetable status (fresh or dehydrated) are indicated in the monograph. The vegetable must be presented in the healthy status, non-decayed, exempt of impurities and microbiological contaminants, as per the legislation in force.

The Aninal Kingdom is also a source for the preparation of homeopathic medicines, however, in a smaller quantity. The animals may be used as a whole, alive or not, recently sacrificed or desiccated, but also in parts or even as extraction/transformation products. The used part and the animal status are indicated in the nonographs.

The Mineral Kingdom provides substances in their natural and/or synthetic status, arising out of chemical-pharmaceutical transformation. The chemical-pharmaceutical products, serum, vaccines, bacterial cultures, opotherapic products, allopathic medicines, cosmectics and others are also used in the preparation of homeopathic medicines.

All of the products used in the preparation of homeopathic medicines must be identified in accordance with the classification rules or scientific technical literature.

6.2 LIST OF THE MOST USED HOMEOPATHIC MEDICINES

Abies canadensis
Abies nigra
Artemisia abrotanum
Artemisia absinthium
Achillea millefolium
Acidum aceticum
Acidum benzoicum
Acidum boracicum
Acidum carbolicum
Acidum chromicum
Acidum citricum
Acidum desoxyribonucleicum
Acidum fluoricum
Acidum gallicum
Acidum formicum
Acidum hidrocyanicum
Acidum lacticum

Acidum muriaticum
Acidum nitricum
Acidum oxalicum
Acidum phosphoricum
Acidum picricum
Acidum ribonucleicum
Acidum salicylicum
Acidum sarcolacticum
Acidum sulphuricum
Acidum uricum
Aconitum napellus
Actaea spicata
Adonis vernalis
Adrenalinum
Aesculus glabra
Aesculus hippocastanum
Aethusa cynapium
Agaricus muscarius
Agnus castus
Agraphis nutans
Ailanthus glandulosus
Aletris farinosa
Allium cepa
Allium sativum
Alloxanum
Aloe socotrina
Althaea officinalis
Alumen
Alumina
Aluminium metallicum
Ambra grisea
Ambrosia artemisiaefolia
Ammonium carbonicum
Ammonium muriaticum
Ammonium nitricum
Ammonium phosphoricum
Amygdalus amara
Amyl nitrosum
Anacardium occidentale
Anacardium orientale
Anagallis arvensis
Angelica archangelica
Anas barbariae hepatis et cordis extractum
Angustura vera
Anilinum
Anthracinum
Antidiphterinum
Antimonium arsenicicum

This translation does not replace the portuguese version.

Antimonium crudum
Antimonium iodatum
Antimonium oxydatum
Antimonium sulphuratum auratum
Antimonium tartaricum
Apis mellifica
Apisinum
Apium graveolens
Apocynum androsaemifolium
Apocynum cannabinum
Aralia racemosa
Aranea diadema
Argentum metallicum
Argentum muriaticum
Argentum nitricum
Aristolochia clematitis
Aristolochia milhomens
Arnica montana
Arsenicum album
Arsenicum iodatum
Arsenicum sulphuratum flavum
Arsenicum sulphuratum rubrum
Arum maculatum
Arum triphyllum
Arundo mauritanica
Asafoetida
Asarum europaeum
Asclepias tuberosa
Aspidosperma
Astacus fluviatilis
Asterias rubens
Atropinum
Atropinum sulphuricum
Aurum iodatum
Aurum metallicum
Aurum muriaticum
Aurum muriaticum natronatum
Aurum sulphuratum
Avena sativa
Aviaria
Badiaga
Baptisia tinctoria
Bacillinum
Baryta acetica
Baryta carbonica
Baryta iodata
Baryta muriatica
BCG

Belladonna
Bellis perennis
Benzinum
Berberis aquifolium
Berberis vulgaris
BFDenys
Betula alba
Bismuthum metallicum
Bismuthum oxydatum
Bismuthum subnitricum
Blatta americana
Blatta orientalis
Borax
Bothrops lanceolatus
Botulinum
Bovista
Bromum
Brucela melitensis
Brucelinum
Bryonia alba
Bufo rana
Cajuputum
Cactus grandiflorus
Cadmium metallicum
Cadmium sulphuratum
Cadmium sulphuricum
Caladium seguinum
Calcarea acetica
Calcarea arsenicica
Calcarea bromata
Calcarea carbonica
Calcarea fluorica
Calcarea iodata
Calcarea muriatica
Calcarea oxalica
Calcarea phosphorica
Calcarea sulphurica
Calculi biliaris
Calculis renalis
Calendula officinalis
Calotropis gigantea
Caltha palustris
Camphora
Cantharis vesicatoria
Capsicum annuum
Carbo animalis
Carbo vegetabilis
Carcinosinum

Carduus marianus
Carum carvi
Cascara sagrada
Cascarilla
Castor equi
Castoreum
Caulophyllum thalictroides
Causticum
Ceanothus americanus
Cedron
Cerasus virginiana
Cereus bomplandii
Matricaria chamomilla
Chelidonium majus
Chenopodium anthelminthicum
Chimaphila umbellata
China officinallis
Chininum arsenicosum
Chininum muriaticum
Chininum purum
Chininum sulphuricum
Chionanthus virginica
Chlorum
Cholesterinum
Chrysarobinum
Cicuta virosa
Cimicifuga racemosa
Cina
Cinnamomum zeylanicum
Cineraria maritima
Cinnabaris
Cistus canadensis
Clematis erecta
Clematis vitalba
Cobaltum metallicum
Cocculus indicus
Coccus cacti
Cochlearia armoracia
Coffea cruda
Coffea tosta
Colchicum autumnale
Colibacilinum
Collinsonia canadensis
Colocynthis
Comocladia dentata
Condurango
Conium maculatum
Convallaria majalis

Copaiva officinalis
Coqueluchinum
Corallium rubrum
Cordia curassavica
Cortisone
Crataegus oxyacantha
Crocus sativus
Crotalus horridus
Croton tiglium
Cuprum aceticum
Cuprum arsenicosum
Cuprum carbonicum
Cuprum metallicum
Cuprum oxidatum nigrum
Cuprum sulphuricum
Curare
Cyclamen europaeum
Cypripedium pubescens
Cyrtopodium punctatum
Daphne indica
Datura arborea
Digitalis purpurea
Dioscorea villosa
Dolichos pruriens
Drosera rotundifolia
Dulcamara
Echinacea angustifolia
Elaps corallinum
Epiphegus virginiana
Equisetum arvense
Equisetum hyemale
Erigeron canadensis
Ethylicum
Eucalyptus globulus
Eugenia jambosa
Eupatorium perfoliatum
Eupatorium purpureum
Euphorbium officinarum
Euphorbia resinífera
Euphrasia officinalis
Fagopyrum esculentum
Ferrum aceticum
Ferrum arsenicicum
Ferrum bromatum
Ferrum carbonicum
Ferrum iodatum
Ferrum lacticum
Ferrum metallicum

This translation does not replace the portuguese version.

Ferrum muriaticum
Ferrum phosphoricum
Ferrum picricum
Ferrum sulphuricum
Filix mas
Folliculinum
Formica rufa
Fragaria vesca
Fraxinus americana
Fucus vesiculosus
Fumaria officinalis
Gambogia
Gelsemium sempervirens
Gentiana lutea
Ginkgo biloba
Glonoinum
Gnaphalium polycephalum
Gossypium herbaceum
Granatum
Graphites
Gratiola officinalis
Grindelia robusta
Guaiacum officinale
Guatteria gaumeri
Hamamelis virginiana
Hedeoma pulegioides
Hedera helix
Hekla lava
Helianthus annuus
Helleborus niger
Heloderma
Helonias dioica
Hepar sulphur
Hipophise lobulo anterior
Hipophise lobulo posteriro
Hipophise total
Histaminum
Hydragium biiodatum
Hydrangea arborescens
Hydrastinum muriaticum
Hydrastis canadensis
Hydrocotyle asiatica
Hyoscyamus niger
Hypericum perforatum
Iberis amara
Ignatia amara
Indigo
Influenzinum

Iodoformum
Iodum
Ipecacuanha
Iris versicolor
Juglans regia
Kali aceticum
Kali arsenicosum
Kali bichromicum
Kali bromatum
Kali carbonicum
Kali chloratum
Kali chloricum
Kali chromicum
Kali cyanatum
Kali ferrocyanatum
Kali iodatum
Kali muriaticum
Kali nitricum
Kali oxalicum
Kali permanganacicum
Kali phosphoricum
Kali sulphuricum
Kalmia latifolia
Kreosotum
Lac caninum
Lac defloratum
Lac vaccinum
Lachesis mutus
Lachnanthes tinctoria
Lapis albus
Lappa major
Latrodectus mactans
Latyrus sativus
Laurocerasus
Ledum palustre
Lemna minor
Leptandra virginica
Lespedeza capitata
Lilium tigrinum
Lithium carbonicum
Lobelia inflata
Luesinum
Luffa operculata
Lycopersicum esculentum
Lycopodium clavatum
Lycopus virginicus
Magnesia carbonica
Magnesia muriatica

This translation does not replace the portuguese version.

Magnesia oxydata
Magnesia phosphorica
Magnesia sulphurica
Magnolia glauca
Hippomane mancinella
Mandragora officinarum
Manganum aceticum
Manganum metallicum
Manganum sulphuricum
Marmoreck
Medicago sativa
Medorrhinum
Melilotus officinalis
Menispermum canadense
Mentha piperita
Menyanthes trifoliata
Mephitis mephitica
Mephitis putorius
Mercurius corrosivus
Mercurius cyanatus
Mercurius dulcis
Mercurius iodatus flavus
Mercurius iodatus ruber
Mercurius solubilis
Mercurius sulphuratus ruber
Mercurius vivus
Mezereum
Mica
Mikania glomerata
Moschus
Murex purperea
Mygale lasiodora
Myrica cerifera
Myristica sebifera
Myrtus communis
Naja tripudians
Naphthalinum
Natrum arsenicum
Natrum bromatum
Natrum carbonicum
Natrum muriaticum
Natrum nitricum
Natrum phosphoricum
Natrum salicylicum
Natrum sulfuricum
Natrum vanadinicum
Niccolum carbonicum
Niccolum metallicum

This translation does not replace the portuguese version.

Niccolum sulphuricum
Nuphar luteum
Nux moschata
Nux vomica
Ocimum canum
Oenanthe crocata
Oleander
Onosmodium virginianum
Opuntia vulgaris
Oreodaphne californica
Origanum majorana
Ornithogalum umbellatum
Osmium metallicum
Paeonia officinalis
Palladium metallicum
Pareira brava
Paris quadrifolia
Passiflora alata
Passiflora incarnata
Paullinia sorbilis
Petroleum
Petroselinum sativum
Phellandrium aquaticum
Phosphorus
Physostigma venenosum
Phytolacca decandra
Pilocarpinum muriaticum
Piper methysticum
Piper nigrum
Plantago major
Platinum metallicum
Platinum muriaticum
Plumbum aceticum
Plumbum carbonicum
Plumbum chromicum
Plumbum iodatum
Plumbum metallicum
Podophyllinum
Podophyllum peltatum
Polygonum punctatum
Populus tremuloides
Pothos foetidus
Progesteronum
Prunus spinosa
Psorinum
Ptelea trifoliata
Pulex irritans
Pulmo histaminum

This translation does not replace the portuguese version.

Pulsatilla
Pyrogenium
Quassia amara
Quercus glandium spiritus
Ranunculus bulbosus
Raphanus sativus
Ratanhia
Rauwolfia serpentina
Rhamnus catharticus
Rhamnus purshiana
Rhamnus californica
Rheum officinale
Rheum palmatum
Rhododendron chrysanthum
Rhus aromatica
Rhus glabra
Rhus toxicodendron
Rhus venenata
Ricinus communis
Robinia pseudoacacia
Rosmarinus officinalis
Rubia tinctorum
Rumex crispus
Ruta graveolens
Sabadilla
Sabal serrulata
Sabina
Saccharium officinale
Salix alba
Salix nigra
Sambucus nigra
Sanguinaria canadensis
Sanguinarinum nitricum
Sanicula aqua
Sarsaparilla
Scilla marítima
Scrophularia nodosa
Scutellaria lateriflora
Secale cornutum
Selenium
Sempervivum tectorum
Senecio aureus
Senega officinalis
Senna
Sepia succus
Serum anguillae
Silicea
Sinapis alba

This translation does not replace the portuguese version.

Sinapis nigra
Solanum nigrum
Solidago virga aurea
Spigelia anthelmia
Spiritus glandium quercus
Spongia tosta
Stannum iodatum
Stannum metallicum
Staphylococcinum
Staphysagria
Stellaria media
Sterculia acuminata
Sticta pulmonaria
Stigmata maydis
Stramonium
Streptococcinum
Strontium carbonicum
Strophanthus hispidus
Strychininum sulfuricum
Strychnos ignatii
Sulphur
Sulphur iodatum
Sumbul
Symphoricarpus racemosus
Symphytum officinale
Syzygium jambolanum
Tabacum
Tanacetum vulgare
Taraxacum officinale
Tarentula cubensis
Tarentula hispanica
Tellurium metallicum
Terebinthina
Teucrium marum
Theridion
Thiosinaminum
Thlaspi bursa pastoris
Thuya occidentalis
Thymus serpyllum
Thyroidinum
Trifolium pratense
Trillium pendulum
Triticum repens
Tuberculinum = TK
Tuberculinum residuum Koch = TR
Tussilago fragrans
Uranium nitricum
Urea

This translation does not replace the portuguese version.

Urtica dioica
Urtica urens
Ustilago maydis
Uva ursi
Valeriana officinalis
Vanadium metallicum
Variolinum
Veratrum album
Veratrum viride
Verbascum thapsus
Vespa crabo
Viburnum opulus
Viburnum prunifolium
Vinca minor
Viola odorata
Viola tricolor
Vipera torva
Viscum album
Wyethia helenioides
Xanthoxylon fraxineum
Yucca filamentosa
Ferrum metallicum
Zincum muriaticum
Zincum valerianicum
Zingiber officinale

This translation does not replace the portuguese version.

This translation does not replace the portuguese version.

7. INERT INPUTS AND PACKAGES

7.1 EXCIPIENTS AND VEHICLES

- Purified water.
- Inert bandages (bandage and others). Bases or inputs for liniments.
- Bases or inputs for creams, gels, gel-cream, lotions, pomades and suppositories. Bases or inputs for post-medicine.
- Bases or inputs for syrups. Inert tablets.
- Inputs for pharmacotechnical adjuvants for solid pharmaceutical forms. Ethanol at 96% (v/v) and its dilutions.
- Glycerol (glycerine) and its dilutions.
- Inert globues and microglobules or inputs to prepare them. Lactose.
- Sucrose. Inert bars.

7.2 PACKAGING MATERIAL

7.2.1 VESSELS

- The use of the following materials are allowed in the operations related as follows.

PREPARATION AND STOCKING OF MEDICINES
- Glass: amber, hydrolytic class I, II, III and NP **(6.1) FB 5**.

MEDICINE DISPENSING
- Glass: amber, hydrolytic class I, II, III and NP **(6.1) FB 5**.
- Plastic: milky white of polyethylene, polypropylene **(6.2.1) FB 5** and polycarbonate.
- Paper: backing paper or any other semi-transparent paper with low permeability to greasy substances.
- Blister.
- Sachet.
- Flacon

7.2.2 ACCESSORIES

- Caps: polyethylene or polypropylene.
- Bung: polyethylene or polypropylene.
- Cannulas: glass, polyethylene, polypropylene or polycarbonate.
- Bulbs: latex, non-toxic silicone or polyethylene.
- Drippers: polyethylene or polypropylene.
- Labels.

This translation does not replace the portuguese version.

This translation does not replace the portuguese version.

8. GENERAL PROCEDURES

8.1 DRUGS OF VEGETABLE ORIGIN

The species of vegetable origin to be used in homeopathy must be collected at proper periods and conditions, followed by the identification, and this identification is complemented at a laboratory by licensed professional.

The vegetable drugs must be used preferably in its fresh status and, in the impossibility of such a procedure, they may be used in its dry status.

The plants used in homeopathy must be in its healthy status, clear of any contamination, pathogenic in nature or others, without any signal of deterioration.

When they are not described in their respective monographs, the raw material of vegetable origin must be collected, preferably, meeting the following general guidance:

1. Entire plants: collected at the flowering time.
2. Leaves: after the complete development of the vegetable, before the flowering time.
3. Flowers and flowered heads: immediately before its full blooming.
4. Stem and branches: after the development of the leaves and before the flowering time.
5. Resinous plant peels: at the period of leaf and bud development, occasion in which there is the highest production of sap.
6. Non-resinous plant peels: at the period of the highest production of sap, in young specimens.
7. Timber or log: from young, however, completely developed specimens.
8. Annual ou biannual plant roots: at the end of the vegetative period.
9. Evergreen plant roots: before completing their vegetative cycle.
10. Fruits and seeds: at its maturity.
11. Buds: at its emergence.
12. Young leaves: right after the bud emergence.

8.2 DRUGS OF ANIMAL ORIGIN

Drugs of animal origin must be obtained from duly identified and zoologically classified specimens, and this identification is complemented at laboratory by licensed professional. Except for different description in the respective monograph, healthy and young animals must be used, however, they must be completely developed.

They may be constituted by entire animals, alive or recently sacrificed, desiccated or not, parts or organs and physiological or pathological secretions, meeting the technical-scientific and hygiene regulations.

8.3 DRUGS OF MINERAL ORIGIN

Drugs of mineral origin must be chemically determined, have their scientific denomination and chemical composition defined.

This translation does not replace the portuguese version.

8.4 DRUGS OF CHEMICAL-PHARMACEUTICAL ORIGIN

The pharmacopoeic regulations must be fulfilled.

8.5 DRUGS OF OTHER ORIGINS, BIOLOGICAL, PATHOLOGICAL OR NOT

The drugs of microbiological origin (bacterial, virotic or fungal), tissues, organs and secretions, must be treated in order to ensure the biosafety. Those arising out of compulsory notification pathologies shall meet the legislation in force.

8.6 DRUGS OF OTHER NATURE

They are medicines whose origin does not fall within any of the previous origins available from other natural or physical resources.

8.7 INERT INPUTS

They must be in accordance with the requirements related to the characterization, identification and quality, meeting the pharmacopoeic regulations.

The obtainment, transportation, storage, handling and/or manipulation of inputs must ensure their quality, particularly concerning the humidity, temperature and odor conditions.

8.8 ALCOHOLIC SOLUTIONS

The alcoholic solutions will be obtained from the mixture of alcohol (ethanol) with purified water, until the desired alcoholic content is obtained (**Annex C**). The used ethanol and purified water must follow the pharmacopoeic requirements.

In the preparation of the mother tinctures, matrices and pharmaceutical forms of internal and external use, liquid, is allowed to adopt the ponderal (p/p) or volumetric (v/v) criterion, or even (v/p) or (p/v), as long as the same criterion is conserved until the end of the operation.

8.9 GLYCERINE-BASED DILUTIONS

Glycerine-based dilutions will be obtained from the mixture of glycerine with purified water and/or ethanol. The used glycerine, ethanol and purified water must follow the pharmacopoeic requirements.

Examples:
- Glycerine + water (1:1)
- Glycerine + ethanol (1:1)
- Glycerine + water + ethanol (1:1:1)

This translation does not replace the portuguese version.

9. ANALYSIS AND TESTING METHODS

9.1 PHYSICAL AND PHYSICAL-CHEMICAL DETERMINATIONS

9.1.1 FLAME TEST

In an acidic medium (concentrated hydrochloric acid) on platinum loop impregnated with the analysis drug, lead it to the non-lightining zone of the Bunsen burner; observe the color transmitted to it. Due to the interference possibility of Na, as a contaminant, in the final result of the analysis, observe the flame color through cobalt blue glass filter.

	Color
Na	Yellow
Ca	Orange-red
Sr	Ruby
Li	Ruby
K	Chlorine violet
Rb	Violaceous
Cs	Blue-violet
Ga	Violet
CN^-	Mallow
Hg_2Cl_2	Violet
Pb	Light blue
Cu	Blue green
As, Sb	Blue-white
Sc	Light blue
Tl	Green
Te	Green
Ba	Light green
$B(OH)_3$	Green
H_3PO_4	Green
Mn	Green
Bi	Light green

9.1.2 DETERMINATION OF THE DRY RESIDUE OF MOTHER TINCTURES (R.S.)

Introduced into porcelain crucible, previously tared, the known amount of the mother tincture. Evaporate in bain-marie until dryness and lead to the greenhouse at the temperature of 100 C a 105 C, until it has constant weight. Each weighing must be preceded by the cooling at the desiccator containing the desiccating agent (silica or anhydrous calcium chloride). Weigh the residue and express the result relatively at 100 g of the mother tincture. When it is a hygroscopic residue, covering the crucible is required for the transfer from the greenhouse to the desiccator and from the disseator to the scale.

This translation does not replace the portuguese version.

9.1.3 DETERMINATION OF THE DENSITY

For the determination of the density, the method described in *Determination of the density of mass and relative density* **(5.2.5) FB 5** is used.

9.1.4 DETERMINATION OF THE ETHANOLIC TITLE OF THE MOTHER TINCTURE (TIT. ET.)

For the determination of the ethanolic title of the mother tinctures, the method described in *Determination of the alcohol* **(5.3.3.8) FB 5** is used.

9.1.5 DETERMINATION OF PH

For the determination of pH, the method described in *Determination of pH* **(5.2.19) FB 5** is used.

9.1.6 SPECTROPHOTOMETRIC DETERMINATION OF ABSORPTION IN ULTRAVIOLET, VISIBLE AND INFRARED

For the spectrophotometric determination of absorption, the method described in *Absorption spectrophotometry in ultraviolet, visible and infrared* **(5.2.14) FB 5** is used.

9.1.7 CHROMATOGRAPHIC DETERMINATION IN THIN LAYER

For the chromatographic determination in thin layer, the method described in *Chromatography in thin layer* **(5.2.17.1) FB 5** is used.

9.1.8 CHROMATOGRAPHIC DETERMINATION IN PAPER

For the chromatographic determination in paper, the method described in *Chromatography in paper* **(5.2.17.2) FB 5** is used.

9.1.9 CHROMATOGRAPHIC DETERMINATION IN COLUMN

For the chromatographic determination in column, the method described in *Chromatography in column* **(5.2.17.3) FB 5** is used.

9.1.10 CHROMATOGRAPHIC DETERMINATION TO HIGH EFFICIENCY LIQUID

For the chromatographic determination for high efficiency, the method described in *Chromatography to high efficiency liquid* **(5.2.17.4) FB 5** is used.

9.1.11 CHROMATOGRAPHIC DETERMINATION TO GAS

For the chromatographic determination to gas, the method described in *Chromatography to gas* **(5.2.17.5) FB 5** is used.

This translation does not replace the portuguese version.

9.1.12 DETERMINATION BY ELECTROPHORESIS

For the determination by electrophoresis, the method described in *Electrophoresis* **(5.2.22) FB 5** is used.

9.1.13 DRIPPING TEST FOR HOMEOPATHIC MEDICINES

The dripping test aims at determining the number of drops per milliliter, for a batch of dripping devices (droppers or drippers), using purified water or ethanol in different gradations.

DETERMINATION OF THE NUMBER OF DROPS PER MILLILITER
The dripping must be made with the cannula coupled to the bulb (dropper) in upright position or glass with dripping device in the proper position and tilting angle.

The test must be performed at the proper temperature (20 °C ± 2 °C). Separate 30 units. Proceed with the test using 10 units.

The standardization of the number of drops per mL for each test solution is required. Use purified water or ethanol in different gradations as test solution. This test shall be performed for every batch of dripping devices.

PROCEDURE
A. For each device, determine the number of drops required to complete a 1 mL volume in a 10 mL calibrated test tube.
B. Record the number of drops contained in this 1 mL.
C. Repeat the process for the 10 tested units.
D. Calculate the mean, standard deviation and relative standard deviation, referring to the number of drops per mL, determined for each unit, according to the expressions:

Mean:

$$\bar{x} = \frac{\sum n}{N}$$

where:
$\bar{x}$ = mean of the results;

$\sum n$ = sum of the number of drops from all of the testes devices;

N = number of tested devices.

Standard deviation:

$$s = \sqrt{\frac{\sum (n_i - \bar{\bar{x}})^2}{n-1}}$$

Relative standard deviation:

$$DPR = \frac{100 \text{ x } s}{\overline{x}}$$

where:

$\overline{x}$ = mean of the results;
s = standard deviation;
n = number of tested units;
DPR = relative standard deviation;
ni = number of tested units.

CRITERIA

- The batch of dripping devices will be validated in case the number of drops, for each of the 10 tested units is between 85.0% and 115.0% of the mean, and the relative standard deviation (*DPR*) is not higher than 6.0%.
- If a unit is out of range from 85.0% to 115.0% of the mean or the *DPR* is higher than 6.0%, test 20 units more.
- The product fulfills the test if, as a maximum, one of the thirty units is out of the range from 85.0% to 115.0% of the mean of calculated drops for the batch, and no unit must exceed the range from 75.0% to 125.0% of the mean and the *DPR* must not be higher than 7.8%.

DETERMINATION OF THE NUMBER OF DROPS PER mL

- In case the batch of drippers fulfills the test, the mean of the found results will be used as the number of drops per mL for this batch of dripping devices.

9.1.14 ALCOHOLOMETRY

- Alcoholometry is the determination of the alcoholic content of the mixtures of water and ethyl alcohol.
- The alcoholometric volumetric title or alcoholic volumetric content of any mixture of water and ethanol is expressed by the number of ethanol volume, at temperature of 20 °C, contained in 100 volumes of this mixture at the same temperature. It is expressed in % (v/v).
- The alcoholometric ponderal title is expressed by the relation between the ethanol mass contained in any mixture of water and ethanol and its total mass. It is expressed in % (p/p).
- The ethyl alcohol contains, as a minimum, 95.1% (v/v), corresponding to 92.55% (p/p) and, as a maximum, 96.9% (v/v), corresponding to 95.16% (p/p) of ethanol (C2H6O) at 20 °C, which may be observed in the alcoholometric table.

DETERMINATION OF THE ALCOHOLOMETRIC TITLE

- The centesimal alcoholometer is a densimeter and it is assigned to the determination of the alcoholic content of the mixtures of water and ethanol, indicating only the ethanol concentration in volume and it is expressed by its measure unit, grade Gay-Lussac - G.L.
- The instrument to determine the alcoholic content is a densimeter named alcoholometer and it indicates the ethyl alcohol volume contained in 100 volumes of a mixture made exclusively of ethyl alcohol and water.

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- The determinations of the alcoholometer are accurate only for the mixture of water and ethanol, at the temperature of 20 °C, at which the instrument was rated. If the temperature during the testing is lower or higher than 20 °C, correcting the temperature of the mixture to 20 °C is required.

PREPARATION OF DILUTED ETHYL ALCOHOL

- For the preparation of the diluted ethyl alcohol, the adoption of the volumetric criterion v/v (volume of the ethanol per water volume) or the ponderal criterion p/p (ethanol weight per water weight) is authorized.

Diluted alcohol preparation technique

- In order to obtain the diluted ethyl alcohol volume in the desired content, calculate the start-up quantity of ethyl alcohol to be used according to the expression:

$$V_p = \frac{V_d \times T_d}{T_p}$$

where:
Vp = volume of the start-up volume of ethyl alcohol to be
used (mL); Vd = volume of the desired diluted ethyl alcohol (mL);
Td = Desired alcoholic content (% v/v);
Tp = Real start-up alcoholic content at 20 °C (% v/v);

Note: *the real start-up alcoholic content must be obtained by using the alcoholometer as per technique to determine the alcoholic content described in this chapter.*

The volume of purified water to be packaged for the obtainment of the desired diluted ethyl alcohol may be found in accordance with the expression:

$$Va = Vd - Vp$$

where:
Va = volume of purified water to be used (mL);
Vd = volume of the desired diluted ethyl alcohol (mL);
Vp = volume of the start-up ethyl alcohol to be used (mL).

In order to prepare the diluted ethyl alcohol, the following instructions must be followed:

- Measure the volume of ethyl alcohol and water separately.
- Make the mixture of both liquids.
- Rest up to the molecule accomodation.
- Check the obtained ethyl alcohol, using the alcoholometer.
- Make the necessary adjustments addeding water or ethyl alcohol. Re-check the obtained ethyl alcohol, using the alcoholometer.
- Repeat the two latest items to achieve the desired value.

Technique for determination of the alcoholic content:

- Place 1000 mL of neutral ethanol on a test tube with the same capacity.
- The lower meniscus of the liquid must be above the line (division).

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- Leave the ethanol for some minutes so that the molecules may accomodate. Place the lower tip of the thermometer. Write the temperature down.
- Dip into the liquid the alcoholometer previously wet in the ethanol in a testing and carefully dried. Print a 360o rotation, anti-clockwise in the alcoholometer, which shall freely float on the test tube, without sticking to the walls.
- When the alcoholometer is not oscillating any longer, gaze at below the liquid surface level. Look up until the visual radius is at the same level as the liquid surface. Read the number of the gradation corresponding to the blooming.
- The correspondence bwtween % v/v (°GL) and % p/p is showed in the **Annex C**.

9.2 CHEMICAL DETERMINATIONS

9.2.1 REACTIONS OF ION, GROUP AND FUNCTION IDENTIFICATION

- **Acetate** For the identification of acetate, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Acetyl.** For the identification of acetyl, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Alkaloids.** For the identification of alkaloids, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Aluminum, ion.** For the identification of aluminum, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Primary aromatic amine.** For the identification of primary aromatic amine, the method described in Ions, groups and functions **(5.3.1.1) FB 5** is used.
- **Amino acids.** For the analysis of the amino acids:
  - The methods described in *Analysis of amino acids* **(5.3.3.9.) FB 5** is used.
  - Dissolve 0.1g of the drug into 5 mL of ethanol at 96% (v/v). Add five drops of the solution of the ninhydrin solution at 0.1% (p/v) in ethanol at 96% (v/v). Heat in boiling bain-marie. A rosaceous or violet color is developed.
- **Volatile aliphatic ammonia and amine.** For the identification of volatim ammonia and amine, the method described in Ions, groups and functions **(5.3.1.1) FB 5** is used.
- **Ammonium, ion.** For the identification of ammonium, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Antimony (III), ion.** For the identification of antimony, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Arsenic.** For the identification of arsenic, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Barbiturate without substitute in the nitrogen.** For the identification of barbiturate, the method described in Ions, groups and functions **(5.3.1.1) FB 5** is used.
- **Barium, ion.** For the identification of ion, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Benzoate.** For the identification of benzoate, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Bicarbonate.** For the identification of bicarbonate, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Bismuth, ion.** For the identification of bismuth, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.

- **Bisulfite.** For the identification of bisulfite, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Borate.** For the identification of borate, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Bromide.** For the identification of bromide, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Calcium, ion.** For the identification of calcium, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Carbonate.** For the identification of carbonate, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Lead, ion.** For the identification of lead, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Cyanide.** For the identification of cyanide, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Citrate.** For the identification of citrate, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Chlorate.** For the identification of chlorate, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Copper (II), ion.** For the identification of copper, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Ester.** For the identification of ester, the method described in *Ions, groups and* functions (5.3.1.1) FB 5 is used.
- **Steroids.** For the analysis of steroids:
  a) The method described in *Identification of steroids by chromatography in thin layer* **(5.3.1.2) FB 5** is used.
  b) Dissolve 0.1g of the drug into 5 mL of ethanol at 96% or chloroform. Add five drops of antimony trichloride solution at 1% of chloroform. Heat until it boils. Observe the color development in accordance with the drug under analysis.
- **Phenols and phenolic acids.** For the analysis of the phenols and phenolic acids:
  a) 0.05 g of the drup is used, diluted into 5 mL of ethanol, add a drop of the reagent formed by the mixture of equap parts, at the time of its use, of iron (III) chloride solution at 1% (p/v) and potassium ferricyanide at 1% (p/v). It is observed the color development which varies from green to intense blue, in accordance with the drug under analysis. Compare with the standard solution, formed by the mixture of 5 mL ethanol and a drop of the reagent iron (III) chloride - ferric ferricyanide.
  b) Treat 50 mg or 0.5 mL of the drug with Millon's reagent (5 g mercury into 10 mL of nitric acid, prepared in hood). Heat in boiling bain-marie. The red color is dissolved. Note: positive reaction for monophenols with the free position.
- **Iron.** For the identification of iron, the method described in *Ions, groups and* functions (5.3.1.1) FB 5 is used.
- **Ferric, ion.** For the identification of ferric ion, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Ferrous, ion.** For the identification of ferrous ion, the method described in *Ions, groups and functions (5.3.1.1) FB 5 is used.*
- **Flavonoids.** At 1 mL of the drug, add a 5 mg fragment of metallic magnesium and 0.5 mL of hydrochloric acid. A color change is observed, varying in accordance with the drug

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under analysis. **Phosphate (or orthophosphate).** For the identification of phosphate or orthophosphate, the method described in Ions, groups and functions **(5.3.1.1) FB 5** is used.

- **Glycides.** For the analysis of glycides:
  a) In a test tube, place 0.01 g of phenil-hydrazine chloridrate, 0.15 g of crystalized sodium acetate and 2 mL of purified water. Stir to dissolve and, as required, heat in bain-maire. Add five drops or 0.05 g of the drug. Stir vigorously to dissolve. A white or yellow precipitation is formed. In case there is no immediate formation of any precipitation, heat to boil, let it cool and stir once more. The heating time required for the formation of the precipitation allows distinguishing glycides among one another. Thus, fructose forms a precipitation in 2 minutes, glycose in 5 minutes. Separate the precipitation, dry and observe the crystals by the microscope. Each glycide forms crystals which group in a different and characteristic way. Determine the melting point of the formed precipitation. Compare with the literature the type of crystal formation and its grouping mode, as well as its respective melting points or melting interval.
- **Reducing glycides.** For the analysis of the reducing glycides:
  a) Dissolve 0.1 g of the drup into 5 mL of purified water. Stir until total dissolution. Add 5 mL of the Fehling's reagent. Heat until it boils. The formation of variable color precipitation is observed, from green-yellow to fire-brick.
  b) The same type of reaction (oxy-reduction) may be verified by replacing the Fehling's reagent with the Tollens' reagent (ammoniacal silver nitrate). Test it by dissolving 0.1 of the drug into purified water. Add 1 mL of the Tollens' reagent. If the reaction is not made cold, heat until it boils. The formation of gray or dark precipitation or the formation of a silver mirror is observed.
- **Fats and oils (lipids).** For the analysis of fats and oils, the method described in *Physical and physical-chemical testing for fats and oils* **(5.2.29) FB 5** is used.
- **Hypophosphite.** For the identification of hypophosphite, the method described in *Ions, groups and functions (5.3.1.1) FB 5 is used*.
- **Iodide.** For the identification of iodide, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Lactic acid.** For the identification of lactic acid, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Lithium, ion.** For the identification of lithium, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Magnesium, ion.** For the identification of magnesium, the method described in *Ions, groups and functions (5.3.1.1) FB 5 is used*.
- **Mercury.** For the identification of mercury, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Mercury (I), ion.** For the identification of mercury I, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Mercury (II), ion.** For the identification of mercury II, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Nitrate.** For the identification of nitrate, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Nitrite.** For the identification of nitrite, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Oxalate.** For the identification of oxalate, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.

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- **Permanganate.** For the identification of permanganate, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Peroxide** For the identification of peroxide, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Potassium, ion.** For the identification of potassium, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Silver, ion.** For the identification of silver, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Salicylate.** For the identification of salicylate, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Sodium, ion.** For the identification of sodium, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Succinate.** For the identification of succinate, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Sulfate.** For the identification of sulfate, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Sulfite.** For the identification of sulfite, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Tartrate.** For the identification of tartrate, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Oxygenated terpenes.** For the analysis of oxygenated terpens, a drop of the same and a drop of the solution of 2,4-dinitrophenylhydrazine at 0.5 % (p/v) is used in a solution of hydrochloric acid 2 *M*. The development of a variable color is observed in accordance with the oxygenated terpene insaturation rate, from yellow to orange-red. For non-oxygenated terpenes, the reaction is negative.
- **Thiocyanate** For the identification of thiocyanate, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Thiosulfate.** For the identification of thiosulfate, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Xanthine.** For the identification of xanthine, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.
- **Zinc, ion** For the identification of zinc, the method described in *Ions, groups and functions* **(5.3.1.1) FB 5** is used.

9.3 ANALYSIS METHODS OF VEGETABLE DRUGS

- **Sampling.** For sampling, the method described in *Sampling* **(5.4.2.1) FB 5** is used.
- **Foreign matter.** For determination of foreign matter, the method descrubed in *Determination of foreign matter* **(5.4.2.2) FB 5** is used.
- **Water.** For determination of water in vegetable drugs, the method described in Determination of water in vegetable drugs **(5.4.2.3) FB 5** is used.
- **Total ashes.** For determination of total ashes in vegetable drugs, the method described in Determination of total ashaes *(5.4.2.4) FB 5* is used.
- **Insoluble ashes in acid.** For determination of insoluble ashes in acid in vegetable drugs, the method described in Determination of insoluble ashes in vegetable drugs *(5.4.2.5) FB 5* is used.

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- **Essential oils.** For determination of essential oils in vegetable drugs, the method described in Determination of essential oils in vegetable drugs *(5.4.2.7) FB 5* is used.
- **Fixed oils.** For determination of fixed oils in vegetable drugs, the methods described in *Determination of fixed oils* **(5.4.2.8) FB 5** is used.
- **Cineol.** For determination of cineol in vegetable drugs, the methods described in *Determination of cineol* **(5.3.3.9) FB 5** is used.
- **Foam index.** For determination of foam index in vegetable drugs, the method described in *Determination of the foam index* **(5.4.2.10) FB 5** is used.
- **Substances extractable by alcohol.** For determination of substances extractable by alcohol in in vegetable drugs, the method described in *Determination of substances extractable by alcohol* **(5.4.2.11) FB 5** is used.

9.4 BIOLOGICAL METHODS

- **Counting of feasible microorganisms in products which do not need to meet the sterility test.** For counting the feasible microorganisms in products which do not need to meet the sterility test, the method described in *Counting of the total number of mesophilic aerobic microorganisms* **(5.5.3.1.2) FB 5** is used.
- **Sterility.** For the assessment of sterility, the method described in *Sterility Test* **(5.5.3.2.1) FB 5** is used.
- **Pathogen research and identification.** For the performance of the pathogen research and identification the method described in *Research of pathogenic microoganisms* **(5.5.3.1.3) FB 5** is used.
- **Toxicity.** For the assessment of the toxicity, the method described in *Toxicity* **(5.5.2.3) FB 5** is used.

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10. METHOD OF PREPARATION OF THE MOTHER TINCTURE

Abbreviation: Mother tinct.
Symbols: TM,
Drug: vegetable or animal

10.1 PREPARATION OF THE MOTHER TINCTURE OF VEGETABLE ORIGIN

Drug: fresh or dehydrated vegetable.
Part used: entire vegetable, part or secretion.
Extracting liquid: ethanol in different gradations, pursuant to the drug monograph. In case there is no specification in monograph, the alcoholic content in the start-up of the extraction shall be 60% (v/v) and in the end of the extraction shall be from 55% (v/v) to 65% (v/v).

Extraction method: maceration or water seepage.

Relation of solid residue/final volume of TM: 1:10 (p/v) (10%).

10.1.1 PREPARATION OF MOTHER TINCTURE FROM DRY PLANTS

They may be prepared by maceration or water seepage.

10.1.1.1 PREPARATION OF MOTHER TINCTURE FROM DRY PLANTS BY MACERATION

PROCEDURE
It consists of leaving the vegetable desiccated, duly divided, by at least 15 days, in contact with total volume of the proper extracting liquid described in the respective monograph in a protected environment of the direct action of light and heat, stirring the vessel on a daily basis. Then, filter and keep the filtered liquid.

Press the residue, filter and join the liquid resulting from this operation to the one previously filtered. Rest for 48 hours, filter and store in a proper way. For mother tinctures whose monographs determine the specified marking content, a concentration adjustment of this marker may be performed by adding ethanol with the same content as the one used for the preparation of the mother tincture.

PACKAGING AND STORAGE
Amber glass vessel, tight closed, protected from heat and direct light.

EXPIRY DATE
To be determined by the manufacturer, in accordance with the legislation in force.

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10.1.1.2 PREPARATION OF MOTHER TINCTURE FROM DRY PLANTS BY WATER SEEPAGE

PROCEDURE
It consists of placing the desiccated, finely divided and tamised vegetable drug (tamis 40 or 60 - **Annex A**), into proper vessel. Add the extracting liquid in sufficient quantity to moisturize the powder and leave in contact for 4 hours. Transfer carefully to the ideal capacity percolator, in order to avoid the formation of preferable channels for solvent runoff. Place sufficient volume of extracting liquid to cover the entire drug and to obtain the desired quantity of mother tincture. Leave it in contact for 24 hours. Filter at the speed of eight drops per minute for every 100 g of the drug, replacing the solvent in order to keep the drug immersed, until the expected volume of mother tincture is obtained. Rest for 48 hours, filter and store in a proper way.

PACKAGING AND STORAGE
Amber glass vessel, tight closed, protected from heat and direct light.

EXPIRY DATE
To be determined by the manufacturer, in accordance with the legislation in force.

10.1.2 PREPARATION OF MOTHER TINCTURE FROM FRESH PLANTS

The mother tinctures obtained from fresh plants are exclusively prepared by maceration. For the preparation of the mother tincture, the determination of the solid residue of the fresh vegetable is required, as described below or in accordance with the respective monograph. With this value, it is possible to calculate the total volume of mother tincture to be obtained, as well as the volume and content of ethanol to be added. Then, the extractive process may be started.

DETERMINATION OF SOLID RESIDUE OF FRESH VEGETABLE
Take a defined weight sample of fresh vegetable, fractionate it into sufficiently reduced fragments, leaving it in a greenhouse at the temperature from 100 °C to 105 °C, until the weight is constant, except when there is any other specification in the monograph. Calculate the percentage of the solid residue in the sample. Calculate the total weight of the solid residue contained in the fresch vegetable.

To calculate the final volume of the mother tincture to be obtained, multiply the value of the solid residue contained in the fresh vegetable by ten (10). The extracting liquid volume to be added will be equivalent to the final volume of mother tincture to be obtained, minus the water volume contained in the fresh vegetable.

The final alcoholic gradation of the extracting liquid must be that specified in the monograph and resulting from the alcoholic mixture added with the water content contained in the plant. In case there is no specification in monographs, the alcoholic content in the start-up of the extraction shall be 60% (v/v) and in the end of the extraction shall be from 55% (v/v) to 65% (v/v), meeting the following guidance:

- Use ethanol at 90% (p/p) for solid residue up to 29% (plants with high contents of water). If the solid residue is lower than 20%, it must be deemed as equal to 20%.

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- Use ethanol at 80% (p/p) for solid residue from 30% to 39% (plants with medium contents of water).
- Use ethanol at 70% (p/p) for solid residue equal to or higher than 40% (plants with low contents of water).

Example 1.
- Fresh vegetable = 1000 g. Solid residue = 20%.
- Total solid residue of the vegetable = 200 g.
- Quantity of water contained in the vegetable = 800 mL
- Alcoholic content of the extracting liquid to be used = 90% (v/v).
- Volume of mother tincture to be obtained = 2000 mL (10 times the total solid residue).
- Volume of alcohol 90% (v/v) to be added: 2000 mL – 800 mL = 1200 mL.
- Relation of solid residue/final volume of TM 1:10 (p/v) (10%).

Example 2.
- Fresh vegetable = 1000 g.
- Solid residue = 32%.
- Total solid residue of the vegetable = 320 g.
- Quantity of water contained in the vegetable = 680 mL
- Alcoholic content of the extracting liquid to be used = 80% (v/v).
- Volume of mother tincture to be obtained = 3200 mL (10 times the total solid residue).
- Volume of ethanol 80% to be added: 3200 mL – 680 mL = 2520 mL.
- Relation of solid residue/final volume of TM 1:10 (p/v) (10%).

MACERATION PROCESS
It consists of leaving the fresh vegetable, duly divided, by at least 15 days, in contact with total volume of the proper extracting liquid described in the respective monograph in a protected environment from the direct light and heat action, stirring the vessel on a daily basis. Then, filter and keep the filtered liquid. Press the residue, filter and join the liquid resulting from this operation to the one previously filtered. Rest for 48 hours, filter and store in a proper way. For mother tinctures whose monographs determine the specified marking content, a concentration adjustment of this marker may be performed by adding ethanol with the same content as the one used for the preparation of the mother tincture.

10.2 PREPARATION OF THE MOTHER TINCTURE OF ANIMAL ORIGIN

- **Drug:** alive animal, recently sacrificed or desiccated.
- **Part used:** entire animal, part or secretion.
- **Extracting liquid:** ethanol (65% to 70% (v/v)), mixture of ethanol, water and glycerine (1:1:1), mixture of water and glycerine (1:1), mixture of ethanol and glycerine (1:1) or any other specificied in the respective monograph.
- **Relation drug/extracting liquid:** 1:20 (p/v) (5%).
- **Process:** maceration.

Leave the animal drug conveniently fragmented or not, in accordance with the respective monograph, in contact with the volume of the extracting liquid equivalent to the final volume of the mother tincture, in a protected environment from direct light and heat action, stirring the vessel on a daily basis. Leave in contact for at least 15 days, when the extracting liquid

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is alcoholic and for at least 20 days, when the extracting liquid is a glycerine. Filter without expressing. Rest for 48 hours, filter and store in a proper way.

PACKAGING AND STORAGE

- Amber glass vessel, tight closed, protected from heat and direct light.

EXPIRY DATE

- To be determined by the manufacturer, in accordance with the legislation in force.

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11. PREPARATION METHODS OF THE DERIVATIVE PHARMACEUTICAL FORMS

The derivative pharmaceutical forms are prepared pursuant to decimal, centesimal and fifty milesimal scales. The preparation must follow Hahnemann's, Korsakov's or Continuous Flow methods. Since there is no correspondence among the scales and methods, any interconversion is prohibited.

11.1 HAHNEMANN'S METHOD

11.1.1 DECIMAL AND CENTESIMAL SCALES

11.1.1.1 INSOLUBLE DRUGS

- **Start-up.** Insoluble drugs, when its solubility is lower than 10% (DH) or 1% (CH) in water or ethanol in different gradations.
- **Inert input.** Lactose in the first three triturations for centesimal scale and first six triturations for decimal scale, except specification otherwise contained in the respective monograph. From 4 CH or 7 DH, use ethanol as inert input in different gradations.
- **Process.** Trituration for the solid phase, dilution and succussion for the liquid phase.

Technique.

1. Divide the total quantity of lactose to be used in three equal parts. One third of the lactose will be placed in porcelain vessel and triturated to cover its pores.
2. Over this third of lactose, place the active input to be triturated, meeting the decimal scale (1 part of active input for 9 parts of inert input) or centesimal scale (1 part of active input for 99 parts of inert input).
3. Homogenize with porcelain or stainless steel spatula.
4. Triturate vigorously for 6 minutes.
5. Scrape, with the porcelain or stainless steel spatule, the triturated input stuck to the vessel and to the pistil for 4 minutes, homogenizing it.
6. Triturate, vigorously, for 6 minutes, no lactose added.
7. Scrape the triturated input for 4 minutes.
8. Add the second third of the lactose.
9. Triturate vigorously for 6 minutes.
10. Scrape the triturated input for 4 minutes.
11. Triturate, vigorously, for 6 minutes, no lactose added.
12. Scrape the triturated input for 4 minutes.
13. Add the last third of lactose.
14. Triturate vigorously for 6 minutes.
15. Scrape the triturated input for 4 minutes.
16. Triturate vigorously for 6 minutes.
17. Scrape the triturated input for 4 minutes.
18. This triturated input will be packaged in a tight closed vessel and protected from the light, receiving the respective homeopathic name and the designation of first triturated input. 1/10 or 1/100. E.g.: *Petroleum* 1 DH trit. or *Petroleum* 1 CH trit.
19. For the obtainment of the second triturated input, 2 DH or 2 CH, use 1 part of the first triturated input as active input, for 9 or 99 parts of lactose (respectively, decimal or centesimal scale) by repeating the previous procedure (items from 3 to 17).

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20. This triturated input will be packaged in a tight closed vessel and protected from the light, receiving the drug name and the designation of second triturated input. E.g.: *Petroleum* 2 DH trit., *Petroleum* 2 CH trit.
21. For the obtainment of the third triturated input, 3 DH or 3 CH, use 1 part of the second triturated input as active input, for 9 or 99 parts of lactose (respectively, decimal or centesimal scale) by repeating the previous procedure (items from 3 to 17).
22. This triturated input will be packaged in a tight closed vessel and protected from the light, receiving the drug name and the designation of third triturated input. E.g.: *Petroleum* 3 DH trit., *Petroleum* 3 CH trit.
23. In the case of trituration under decimal scale (DH) for the obtainment of the subsequent triturations, repeat the previous procedure up to the obtainment of the sixth trituration (items 3 to 17).
24. To solubilize the tritured input:
    a) To solubilize to 6 DH trit., considering that it is not soluble cold in the proportion of 1/10 (p/v), heat the purified water at the temperature from 40 °C to 45 °C. Add 10 parts of this heated water over 1 part of 6 DH trit. and homogenize until the dissolution and cooling is complete. Then, succuss 100 times to obtain the 7 DH. This intermediate preparation may not be stocked. To prepare the 8 DH, dilute 1 part of the 7 DH into 9 parts of ethanol at 30% (v/v) to dispense and equal to or higher than 77% (v/v) to stock.
    b) To solubilize the 3 CH trit., dissolve 1 part of this trituration into 80 parts of purified water, complete with 20 parts of ethanol at 96% (v/v) and succuss 100 times to obtain 4 CH. This intermediate preparation may not be stocked. Further dynamizations will be prepared in ethanol in gradation equal to or higher than 77% (v/v) to stock and ethanol at 30% (v/v) to dispense.

- **Packaging and Storage.** Tight closed vessel, protected from heat, humidity and direct light.
- **Expiry Date** To be determined, case by case, as per the pertinent legislation.

11.1.1.2 SOLUBLE DRUGS

- **Start-up.** Mother tincture, soluble water in water or ethanol of different gradations with solubility equal to or higher than 10% (DH) or 1% (CH).
- **Inert input.** Purified water or ethanol in different gradations. In the first three dynamizations, for the centesimal scale and in the first six dynamizations for the decimal scale, ethanol will be used with the same content of the mother tincture or, in the case of soluble mineral, use purified water or alcoholic solutions which solubilizes it. To stock and prepare further derivative forms, use ethanol at 77% (v/v) or higher. For dispensing, both in centesimal and decimal scale, use ethanol at 30% (v/v). In the case of medicines at potencies up to 3 CH and 6 DH, inclusive, dispense in the same alcoholic content as the start-up, placing a remark that "it shall be administered diluted into water at the time of its use".
- **Process.** Dilution and succussion, manual or mechanical.

Technique.

1. Dispose over the bench as many vials as required to achieve the desired dynamization.
2. Place into each vial, volume of inert input in the indicated proportion, as per decimal or centesimal scales.
3. Add into the 1st vial 1 start-up part in 9 (DH) or 99 (CH) parts of the inert input. Succuss 100 times. Thus, 1 DH or 1 CH is obtained.

This translation does not replace the portuguese version.

4. Transfer to the 2nd vial 1 part of the 1 DH or 1 CH in 9 or 99 parts of the inert input, respectively. Succuss 100 times. Thus, 2 DH or 2 CH is obtained.
5. Transfer to the 3rd vial 1 part of the 2 DH or 2 CH in 9 or 99 parts of the inert input, respectively. Succuss 100 times. Thus, 3 DH or 3 CH is obtained.
6. Proceed equally for the subsequent preparations until the desired dynamization is achieved.

- **Number of vials.** As many vials as the dynamizations to be prepared.
- **Volume.** The liquid to be dynamized shall occupy from 1/2 to 2/3 of the capacity of the vial used in the preparation.
- **Number of succussions.** 100.
- **Packaging and Storage.** Tight closed vessel, protected from heat, humidity and direct light.
- **Expiry Date** To be determined, case by case, as per the pertinent legislation.

11.1.2 FIFTY MILESIMAL SCALE

- **Start-up.** Vegetable, animal or biological drug, as much as possible in the fresh status, and mineral drug. The mother tincture may be used, having its medicinal power corrected with further evaportation.

Note: *in the event of using the TM as start-up, correct the medicinal power. After covering the pores on the vessel, the TM will be added to the first third of lactose (when preparing 1 CH trit.). After evaporating, at a temperature lower than 50 °C, proceed with the trituration technique.*

Examples.

A TM of vegetable origin (10%) has a medicinal power of 1/10, namely, 1 part of the drug is contained in 10 parts of TM. For the 1st centesimal tritutation, place 10 parts of the TM for 100 parts of lactose. For TM of animal origin (5%), the medicinal power is 1/20, namely, place 20 parts of the TM for 100 parts of lactose.

- **Inert input.** Purified water, lactose, microglobules and ethanol in different gradations.
- **Volume.** For the liquid phase, the liquid to be dynamized shall occupy from 1/2 to 2/3 of the capacity of the vial used in the preparation.
- **Number of succussions.** 100.
- **Process.** For the solid phase, trituration; for the liquid phase, dilution and succussion, manual or mechanical.

Technique.

1. First stage. Trituration of the drug up to 3 CH trit., as per trituration technique.
2. Second stage. Dissolution of the 3rd trituration.
   - Weigh 63 mg of the 3rd tritutation and dissolve into five hundred drops of ethanol at 20% (v/v).
3. Third stage. Preparation of the 1st dynamization LM (1 LM).
   - In a proper capacity vial, place one drop of the previous solution in 100 drops of ethanol at 96% (v/v).
   - Appply 100 succussions.
   - Moisturize 500 microglobules with one drop of this solution (100 microglobules must correspond to 63 mg).
   - Let it dry at room temperature. This is the matrix in the potency 1 LM.
4. Fourth stage. Preparation of the 2nd potency LM (2 LM).

This translation does not replace the portuguese version.

  - In proper capacity vial, dissolve one microglobule from the 1 LM into a drop of purified water.
  - Add 100 drops of ethanol of 96%.
  - Appply 100 succussions.
  - Moisturize 500 microglobules with one drop of the previous intermediate solution.
  - Separate them quickly on the filter paper, let them dry at room temperature. This is the matrix in the potency 2 LM.
5. Fifth stage. Preparation of further potencies LM.
  - In proper capacity vial, dissolve one microglobule from the immediately previous LM into a drop of purified water.
  - Add 100 drops of ethanol of 96%.
  - Appply 100 succussions.
  - Moisturize 500 microglobules with one drop of the previous intermediate solution.
  - Let it dry at room temperature.

- **Packaging and Storage.** Amber glass vessel, tight closed, protected from heat, humidity, radiations and direct light.
- **Expiry Date** To be determined, case by case, as per the pertinent legislation.

11.2 KORSAKOV'S METHOD

- **Start-up.** Matrix in the potency 30 CH in ethanol at 77% (v/v).
- **Inert input.** Ethanol at 77% (v/v) in the intermediate preparations and ethanol at 30% (v/v) in the dispensing.
- **Number of vials.** Single vial.
- **Volume.** The liquid to be dynamized shall occupy from 1/2 to 2/3 of the capacity of the vial.
- **Scale.** Not defined.
- **Number of succussions.** 100.
- **Process.** Dilution and succussion. Manual or mechanical.
- **Technique.** Place into a vial the sufficient capacity of the matrix in the potency 30 CH in order to occupy from 1/2 to 2/3 of its respective capacity. Keel the vial, letting the liquid to runoff freely for five seconds. Add the inert input in the previously established quantity and succuss for 100 times. The result of this operation sequence corresponds to 31 K. Repeat this procedure to obtain the subsequent dynamizations.

  The dispensing of the medicine prepared in accordance with Korsakov's method must take place from 31 K to 100,000 K as the maximum limit.

  The stocking of medicines prepared through this method is prohibited.

- **Packaging and Storage.** Amber glass vessel, tight closed, protected from heat, humidity, radiations and direct light.
- **Expiry Date** To be determined, case by case, as per the pertinent legislation.

11.3 CONTINUOUS FLOW METHOD

- **Start-up.** Matrix in the potency 30 CH in ethanol at 77% (v/v).
- **Inert input.** Purified water.
- **Number of vials.** Single dynamization chamber.

This translation does not replace the portuguese version.

- **Outflow control.** It must be ensured that a continuous and constant flow of inert input passes through the dynamization chamber in a controlled way so that, in the end of 100 rotations, the content of the chamber is completely renewed.
- **Scale.** Not defined.
- **Number of rotations.** In this method, it is considered that 100 rotations are equivalent to 100 succussions, because at every 100 rotations, a new potency is obtained.
- **Process.** Continuous dilution and whirling. Mechanical.

Mandatory equipment characteristics.
- The dynamization chamber shall have the known volumetric capacity and diluent inlet and outlet system, so that this volume is kept constant throughout the process.
- The water inlet must take place at the vortex center of the liquid under dynamization, so that the purified water entering the chamber is whirled before being expelled.
- The outflow must be synchronized with the number of rotations per minute of the engine, as per the equipment manual.
- The desired potency will take place in virtue of the time required for its obtainment. Upon achieving the defined time, shutdown, on a simultaneous basis, the water inlet and the equipment engine.
- Remove from the dynamizing chamber the volume required so that, then, two Hahnemman's centesimal dynamizations are made in ethanol at 77% (v/v) or higher.

Technique.
- Add the start-up matrix volume in ethanol at 77% (v/v) or higher, equivalent to the volumetric capacity of the apparatus chamber. The purified water inlet and the rotation of the engine will be simultaneously added.
- The dynamization is started at all times with the full chamber.
- The process will be restarted with the last potency FC in which it was interrupted, by adding the start-up matrix volume equivalent to the volumetric capacity of the apparatus chamber.
- Add, then, the purified water inlet and the engine, simultaneously.
- Interrupt the process two potencies before the desired one at all times.
- For the preparation of the last two potencies, Hahnemman's method in centesimal scale will be followed, using ethanol at 77% (v/v) or higher as inert input.
- Only the potencies in ethanol at 77% (v/v) may be stocked.

  The dispensing of the medicine prepared in accordance with *Continuous flow method* must be from 200 FC to 100,000 FC, as its maximum limit.

- **Packaging and Storage.** Amber glass vessel, tight closed, protected from heat, humidity, radiations and direct light.
- **Expiry Date** To be determined, case by case, as per the pertinent legislation.

This translation does not replace the portuguese version.

This translation does not replace the portuguese version.

12. PREPARATION METHODS OF THE PHARMACEUTICAL FORMS FOR DISPENSING

12.1 PHARMACEUTICAL FORMS FOR INTERNAL USE

The quotations referring to the dynamizations of the derivative forms appearing in the monographs published in the Brazilian Homeopathic Pharmacopoeia, concerning the dispensing item, are a result of the toxicity and/or possible physical-chemical incompatibilities between the active input and inert input.

12.1.1 LIQUID FORMS

12.1.1.1 SINGLE LIQUID DOSE

Limited quantity of liquid medicine to be taken at once.

- **Start-up.** Matrix in the desired potency.
- **Inert input.** Purified water or ethanol up to 5% (v/v).
- **Technique.** Dilute the start-up into the inert input in the desired proportion.
- **Volume of preparation and dispensing.** As requested. When it is not specified in the prescription, they will dispensed in the proportion of two drops of the start-up per mL of the inert input, up to a maximum volume of 10 mL.

12.1.1.2 DROPS

Oral solution to be administered in the form of drops.

- **Start-up.** Active input in the previous potency in relation to the desired one. At the LM scale, the start-up is the microglobule in the desired potency.
- **Inert input.** Ethanol at 30% (v/v). In the case of medicines in the potencies up to 3 CH or 6 DH inclusive, use the same alcoholic content as the start-up.
- **Technique.** Dynamize the desired medicine in ethanol at 30% (v/v), from the active input in the potency previous to the desired one. In the case of medicines in the potencies up to 3 CH or 6 DH inclusive, use for the preparation and dispensing the same alcoholic content as the start-up.
- **Volume of preparation.** As desired.
  In the LM scale, dissolve one microglobule of the medicine in the desired potency into one drop of purified water and add ethanol at 30% (v/v); the dispensed volume shall occupy 2/3 of the vial capacity.
- **Dispensing:** The medicine will be dispensed in the desired dynamized volume in ethanol at 30% (v/v). In the case of medicines at potencies up to 3 CH and 6 DH, inclusive, dispense in the same alcoholic content as the start-up, placing a remark that “it shall be administered diluted into water at the time of its use”.

12.1.2 SOLID FORMS

- **Inert inputs.** Lactose, globules, bars and tablets.

This translation does not replace the portuguese version.

12.1.2.1 SINGLE SOLID DOSE

Limited quantity of solid medicine to be taken at once.

- **Start-up.** Active input in the desired potency.
- **Technique.** Impregnate the solid form with two drops of the active input or as prescribed.
- **Dispensing:** When it is not indicated in the prescription, dispense:
  - tablets: one (1) tablet;
  - globules: five (5) globules;
  - powder: 300 to 500 mg of lactose;
  - bar: one (1) bar

12.1.2.2 TABLETS

The tablets have their weight normally between 100 mg and 300 mg. In the preparation of inert tablets, for posterior impregnation, the addition of adjuvants will be allowed in any quantity which does not make their impregnation capacity difficult.

1. *When the active input is liquid:*

Technique.

- **Compression**
  - Prepare the liquid active input in the desired potency.
  - Impregnate this preparation in the proportion of 10% (v/p) as a minimum, in lactose, with or without adjuvants added.
  - Lead to direct compression with or without previous granulation.
  - In order to granulate, as required, moisturize with sufficient quantity of alcoholic solution. Tamis and dry at a temperature not higher than 50 °C.
- **Impregnation**
  - Prepare the liquid active input, in the desired potency, in ethanol 77% (v/v) (equivalent to 70% (p/p)) or higher.
  - Impregnate the inert tablets with the liquid active input in the proportion of 10% (v/p) as a minimum.
  - As required, the drying will be made separately, medicine by medicine, at a temperature not higher than 50 °C.

2. *When the active input is solid:*

Technique.

- **Compression**
  - Prepared the active input, by trituration, in the desired potency.
  - Mix this preparation in the proportion of 10% (p/p) as a minimum, in lactose, with or without adjuvants added.
  - Lead to direct compression or with previous granulation.
  - In order to granulate, as required, moisturize with sufficient quantity of alcoholic solution.

3. *When the active inputs are solid and liquid:*

Technique.

- The total of active inputs must amount in the minimum of 10% of the formulation.
- Divide this proportion by the number of active inputs, solid and liquid, of the formulation.
- Separately prepare the solid active inputs by trituration, in the desired potency, in equal and sufficient quantities to compose this stage.
- Mix and homogenize the solid preparations.

This translation does not replace the portuguese version.

- Separately prepare the liquid active inputs, in the desired potency, in equal and sufficient quantities to compose this stage.
- Mix and homogenize the liquid preparations.
- Weigh the total lactose of the formulation, with or without adjuvants added, discounting the solid phase.
- Add the liquid phase to this lactose and homogenize it
- Then, add the solid phase to this mixture and homogenize it
- Lead to direct compression or with previous granulation, after drying in greenhouse at a temperature not higher than 50 °C.
- The drying will be made separately, medicine by medicine, at a temperature not higher than 50 °C.

12.1.2.3 GLOBULES

The globules are constituted of sucrose or mixture of sucrose and lactose. They are presented as small balls weighing 30 mg (No 3), 50 mg (No 5) and 70 mg (No 7).

Technique.

- **Impregnation**
  - Prepare the liquid active input, in the desired potency, in ethanol equal to or higher than 77% (v/v) (equivalent to 70% (p/p)).
  - Impregnate the inert globules with the liquid active input in the proportion of 5% (v/p) as a minimum.
  - The drying will be made separately, medicine by medicine, at a temperature not higher than 50 °C.

12.1.2.4 POWDERS

The internal use powders will be constituted of active input, in the desired potency, conducted in lactose.

1. *When the active input is liquid:*

Technique.

- **Impregnation**
  - Prepare the liquid active input, in the desired potency, in ethanol at 77% (v/v) (equivalent to 70% (p/p)) or higher.
  - Impregnate the lactose with the liquid active input in the proportion of 10% (v/p) as a minimum.
  - Divide in portions from 300 mg to 500 mg, as the case may be.
  - The drying will be made separately, medicine by medicine, at a temperature not higher than 50 °C.

2. *When the active input is solid:*

Technique.

- **Mixture.**
  - Prepared the active input, by trituration, with lactose in the desired potency.
  - Mix this preparation, in the proportion of 10% (p/p), in lactose and homogenize it
  - Divide in portions from 300 mg to 500 mg, as the case may be.

3. *When the active inputs are solid and liquid:*

Technique.

- **Impregnation and Mixture**

- The active inputs must amount 10% (p/p) of the formulation.
- Divide this proportion by the number of active inputs of the formulation.
- Separately prepare the solid active inputs by trituration, in the desired dynamization, in equal and sufficient quantities to compose this stage.
- Mix and homogenize the solid preparations.
- Separately prepare the liquid active inputs in ethanol at 77% (v/v) (equivalent to 70% (p/p)) or higher, in the desired dynamization, in equal and sufficient quantities to compose this stage.
- Mix the liquids in equal and sufficient parts to compose this stage.
- Weigh the lactose, discounting the solid phase.
- Add the liquid phase to the lactose and homogenize it
- Then, add the solid phase to this mixture and homogenize it
- Divide in portions from 300 mg to 500 mg, as the case may be.
- The drying will be made separately, at a temperature not higher than 50 °C.

12.1.2.5 BARS

Bars are solid pharmaceutical forms which are presented with weight comprised between 75 mg and 150 mg, being prepared by lactose molding in bar containers, without adjuvants added.

1. *When the active input is liquid:*

Technique.

- **Impregnation**
  - Prepare the liquid active input, in the desired potency, in ethanol 77% (v/v) (equivalent to 70% (p/p)) or higher.
  - Impregnate the inert bars with the liquid active input in the proportion of 10% (v/p) as a minimum.
  - The drying will be made separately, medicine by medicine, at a temperature not higher than 50 °C.
- **Molding**
  - Prepare the liquid active input, in the desired potency, in ethanol at 77% (v/v) (equivalent to 70% (p/p)) or higher.
  - Impregnate the lactose with the liquid active input in the proportion of 10% (v/p) as a minimum, homogenize and mold until it is ready with the addition of sufficient quantity of ethanol at 77% (v/v) (equivalent to 70% (p/p)) or higher.
  - Lead to the bar container and mold.
  - Proceed with the extrusion and dry at a temperature not higher than 50 °C.

2. *When the active input is solid:*

Technique.

- **Molding**
  - Prepared the active input, by trituration, with lactose in the desired potency.
  - Mixture this preparation in the proportion of 10% (p/p) as a minimum, homogenize and mold until it is ready with the addition of sufficient quantity of ethanol at 77% (v/v) (equivalent to 70% (p/p)) or higher.
  - Lead to the bar container and mold.
  - Proceed with the extrusion and dry at a temperature not higher than 50 oC.

This translation does not replace the portuguese version.

3. *When the active inputs are solid and liquid:*

Technique.

- The total of active inputs must amount in the minimum of 10% of the formulation.
- Divide this proportion by the number of active inputs of the formulation.
- Separately prepare the solid active inputs by trituration, in the desired potency, in equal and sufficient quantities to compose this stage.
- Mix and homogenize the solid preparations.
- Separately prepare the liquid active inputs in ethanol at 77% (v/v) (equivalent to 70% (p/p)) or higher, in the desired potency, in equal and sufficient quantities to compose this stage.
- Mix and homogenize the liquid preparations.
- Weigh the lactose, discounting the solid phase.
- Add the liquid phase to the lactose and homogenize it
- Then, add the solid phase to this mixture (lactose + liquid phase) and homogenize it
- Lead to the bar container and mold.
- Proceed with the extrusion and dry at a temperature not higher than 50 °C.

12.1.3 PHARMACEUTICAL FORMULATIONS

12.1.3.1 LIQUID FORMULATIONS

1. *With a liquid input:*

Technique.

- Dilution of the active input into the proper volume of inert input.

Examples.

a) *Lycopodium clavatum* 30 CH. . . . . XX drops
Purified water . . . . . 30 mL
or,
Lycopodium clavatum 30 CH . . . . . XX/30 mL

b) *Lycopodium clavatum* 30 CH . . . . . X drops
Ethanol at 96% (v/v) . . . . . V drops
Purified water . . . . . 30 mL
or,
Lycopodium clavatum 30 CH . . . . . X/V/30 mL

c) *Lycopodium clavatum* 30 CH 1%
Ethanol at 30% (v/v) . . . . . qsp 30 mL

2. *With more than one active input:*

Technique.

- Separately prepare, in the desired dynamizations, the medicines appearing in the formulation in ethanol at 30% (v/v). In the case of medicines with active inputs in the potencies up to 3 CH or 6 DH inclusive, use for the preparation the same alcoholic content as the start-up.
- Mix these preparations in equal parts or proper proportions for the indicated volume:

Examples.

a) *Belladona* 6 CH . . . . . } ãã . . . 30 mL
Phytolacca dec. 6 CH . . . . . }

Procedure: mix 30 mL of each medicine, obtaining the final volume of 60 mL.

b) *Belladona* 6 CH . . . . . } ãã . . . qsp . . . 30 mL
Phytolacca dec. 6 CH . . . . . }

Procedure: mix 15 mL of each medicine, obtaining the final volume of 30 mL.

c) *Belladona* 6 CH 1%
Phytolacca dec. 6 CH 2%
Ethanol at 30% (v/v) . . . . . qsp . . . 30 mL

Procedure: mix 0.3 mL (1%) of *Belladona* 6 CH with 0.6 mL (2%) of *Phytolacca dec*. 6 CH and complete the volume for 30 mL with alcohol at 30% (v/v).

12.1.3.2 SOLID FORMULATIONS

12.1.3.2.1 Tablets

1. *With two or more liquid active inputs:*

Technique.

- **Compression**
  - Separately prepare the medicines appearing in the formulation, in the desired potencies, in ethanol at 77% (v/v) (equivalent to 70% (p/p)) or higher.
  - Mix these preparations in equal and sufficient parts; homogenize it
  - Impregnate this preparation, in the proportion of 10% (v/p) as a minimum, in lactose or mixture of lactose and sucrose.
  - Lead to compression with or without previous granulation.
  - In order to granulate, moisturize with sufficient quantity of ethanol at 77% (v/v) (equivalent to 70% (p/p)) or higher.
  - Tamis and dry in greenhouse at a temperature not higher than 50 °C.
- **Impregnation**
  - Separately prepare the active inputs appearing in the formulation, in the desired potencies, in ethanol at 77% (v/v) (equivalent to 70% (p/p)) or higher.
  - Mix these preparations in equal and sufficient parts; homogenize it
  - Impregnate the inert tablets with this mixture, in the proportion of 10% (v/p) as a minimum and homogenize it
  - The drying will be made separately, medicine by medicine, at a temperature not higher than 50 °C.

Example.

Arsenicum album 6 CH
China 6 CH
} ãã . . . . qsp 20 tablets

2. *With two or more solid active inputs:*

Technique.

- **Compression**
  - Prepare by trituration, separately, the active inputs appearing in the formulation, in the desired potencies, with lactose or mixture of lactose and sucrose.
  - Mix these preparations in equal and sufficient parts; homogenize it
  - Mix this preparation, in the proportion of 10% (p/p) as a minimum, in lactose or mixture of lactose and sucrose and homogenize it
  - Lead to compression with or without previous granulation.
  - In order to granulate, moisturize with sufficient quantity of ethanol at 77% (v/v) (equivalent to 70% (p/p)) or higher.
  - Tamis and dry in greenhouse at a temperature not higher than 50 °C.

This translation does not replace the portuguese version.

Example.

Calcarea carbonica 3 CH trit.
Graphites 3 CH trit. } ãã . . . qsp 20 tablets

3. *With solid and liquid active inputs:*

Example.

Calcarea carb. 3 DH trit.
Calcarea phosph. 3 DH trit. } ãã . . . . . qsp 5%

China officinalis 3 CH
Avena sativa 3 CH } ãã . . . . . qsp 5%

Lactose . . . . . qsp . . . . . 80 tablets

- **Preparation.**
  - Total weight of the formulation → 80 x 0.300g = 24 g.
  - Total volume of the liquid active inputs (5%) → 1.2 mL.
  - Volume of each liquid active input (2.5%) → 0.6 mL.
  - Total weight of the solid active inputs (5%) → 1.2 g.
  - Weight of each solid active input (2.5%) → 0.6 g.
  - Total weight of the lactose and excipients (total weight of the formulations minus total weight of the solid active inputs) → 24.0 g – 1.2 g = 22.8 g.
  - Mix and homogenize the solid phase → 0.6 g x 2 = 1.2 g.
  - Add the liquid phase to the lactose and excipients (22.8 g) and homogenize it
  - Then, add the solid phase to this preparation and homogenize it
  - Lead to compression with or without previous granulation.
  - If the granulation is required, moisturize with sufficient quantity of ethanol at 77% (v/v) (equivalent to 70% (p/p)) or higher.
  - Tamis and dry in greenhouse at a temperature not higher than 50 °C.

12.1.3.2.2 Globules

1. *With two or more liquid active inputs:*

Technique.

- Separately prepare the active inputs appearing in the formulation, in the desired potencies, in ethanol at 77% (v/v) (equivalent to 70% (p/p)) or higher.
- Mix these preparations in equal and sufficient parts and homogenize it
- Impregnate the inert globules with the mixture prepared above, in the proportion of 5% (v/p) as a minimum.

Example.

Paeonia officinalis 6 CH
Hamamelis 6 CH } ãã . . . . . qsp . . . . . 15 g glob.

12.1.3.2.3 Powders

1. *With two or more liquid active inputs:*

Technique.

- Separately prepare the active inputs appearing in the formulation, in the desired potencies, in ethanol at 77% (v/v) (equivalent to 70% (p/p)) or higher.

- Mix these preparations in equal and sufficient parts; homogenize it
- Impregnate the lactose with this mixture in the proportion of 10% (v/p) as a minimum.
- Divide in the portions from 300 mg to 500 mg and package in papers, sachets and flacons.

Example.

Hamamelis 6 CH
Aesculus hipocastanum 6 CH } ãã . . . qsp . . . 6 papers, sachets or flacons

2. *With two or more solid active inputs:*

Technique.

- Prepare by trituration, separately, the active inputs appearing in the formulation, in the desired potencies.
- Mix these preparations in equal and sufficient parts or in the formulated proportion and homogenize it
- Mix this preparation in the proportion of 10% (p/p) as a minimum.
- Divide in the portions from 300 mg to 500 mg and package in papers, sachets and flacons.

Example.

Calcarea carbonica 3 CH trit.
Calcarea phosphorica 3 CH trit. } ãã.....qsp 6 papers, sachets or flacons

3. *With solid and liquid active inputs:*

Technique.

- Proceed with as described in *Powders* **(12.1.2.4)**.

Example.

Calcarea carb. 3 DH trit.
Calcarea phosph. 3 DH trit. } ãã . . . . . qsp 5%

China officinalis 3 CH
Avena sativa 3 CH } ãã . . . . . qsp 5%

Lactose . . . qsp . . . . . 60 papers of 500 mg

Procedure:

Mix 0.75 g (2.5%) (p/p) of *Calcarea carb*. 3 DH trit. with 0.75 g (2.5%) (p/p) of *Calcarea phosph*. 3 DH trit.. Mix 0.75 mL (2.5%) (v/p) of *China officinalis* 3 CH with 0.75 mL (2.5%) (v/p) of *Avena sativa* 3 CH. Mix 5% (p/p) of the solid phase with sufficient quantity of lactose for the formulation and homogenize it To this preparation, mix 5% (v/p) of the liquid phase and homogenize it Divide in the portions from 300 mg to 500 mg and package in papers, sachets and flacons.

Preparation

- Total weight of the formulation → 60 papers x 0.50 g = 30 g.
- Total weight of the solid active inputs (5%) = 1.50 g.
- Weight of each solid active input (2.5%) → 0.75 g.
- Total volume of the liquid active inputs (5%) → 1.5 mL.
- Weight of each liquid active input (2.5%) → 0.75 mL.
- Mix and homogenize the solid phase → 0.75 g x 2 = 1.5 g.
- Mix and homogenize the liquid phase → 0.75 g x 2 = 1.5 g.

This translation does not replace the portuguese version.

- Total weight of the lactose and excipients (total weight of the formulations minus total weight of the solid inputs) → 30 g – 1.5 g = 28.50 g.
- Add the liquid phase to the lactose (28.50 g) and homogenize it
- Then, add the solid phase to this preparation and homogenize it
- Dry, as required, in greenhouse at a temperature not higher than 50 °C and tamis.
- Divide in the portions from 300 mg to 500 mg and package in papers, sachets and flacons.

12.1.3.2.4 Bars

1. *With two or more liquid active inputs:*

Technique.

- **Impregnation**
  - Prepare inert bars, by molding of the lactose, in bar container, until the molding is ready with sufficient quantity of ethanol at 77% (v/v) (equivalent to 70%) (p/p)) or higher.
  - Separately prepare the active inputs appearing in the formulation, in the desired potencies, in ethanol at 77% (v/v) (equivalent to 70% (p/p)) or higher.
  - Mix these preparations in equal and sufficient parts and homogenize it
  - Proceed with in accordance with the impregnation technique in *Bars* **(12.1.2.5)**.
- **Molding**
  - Separately prepare the active inputs appearing in the formulation, in the desired potencies, in ethanol at 77% (v/v) (equivalent to 70% (p/p)) or higher.
  - Mix these preparations in equal and sufficient parts and homogenize it
  - Add this preparation in the proportion of 10% (v/p) as a minimum in lactose, homogenize and mold until it is ready with the addition of sufficient quantity of ethanol at 77% (v/v) (equivalent to 70% (p/p)) or higher.
  - Lead to the bar container and mold.
  - Proceed with the extrusion and dry at a temperature not higher than 50 °C.

Example.

Apis mellifica 6 CH
Ledum palustre 6 CH } ãã . . . . . qsp 30g bar.

2. *With two or more solid active inputs:*

Technique.

- **Molding**
  - Prepare by trituration, separately, the active inputs appearing in the formulation, in the desired potencies.
  - Mix these preparations in equal and sufficient parts and homogenize it
  - Mix this preparation in the proportion of 10% (p/p) as a minimum in lactose.
  - Proceed with the molding.

Example.

a) *Calcarea carbonica* 3 CH trit.
Ferrum metallicum 3 CH trit. } ãã . . . . . qsp 30 tabl.

b) *Calcarea carb*. 3 DH trit 5%
Baryta carb. 3 DH trit 5%
Lactose . . . qsp . . . . . 100 g
Ethanol at 77% (v/v) (equivalent to 70% (p/p)) or higher. . . . . qs

This translation does not replace the portuguese version.

Preparation:
- Total weight of the formulation = 100 g.
- Weight of each solid active input (5%) → 5 g.
- Total weight of the solid active inputs (5% x 2) = 10 g.
- Mix and homogenize the solid phase.
- Total weight of the lactose and excipients (total weight of the formulation minus the total weight of the active inputs) → 100 g – 10 g = 90 g;
- Then, add the solid phase to this lactose and homogenize it
- Mold until it is ready with sufficient quantity of ethanol at 77% (v/v) (equivalent to 70% (p/p)) or higher.
- Lead to the bar container and proceed with the molding.
- Proceed with the extrusion. Dry, as required, at a temperature not higher than 50 °C and tamis.

3. *With solid and liquid active inputs:*

The active inputs of the solid phase will be prepared by tritutation, separately, in the desired potencies.

Technique.
- Mix these preparations, in equal and sufficient parts of 10% (p/p) as a minimum or in the proportions of the formulation and homogenize them to compose this stage.
- Mix and homogenize the solid phase.
- Separately prepare the liquid active inputs in ethanol at 77% (v/v) (equivalent to 70% (p/p)) or higher, in the desired potency, in sufficient quantities to compose this stage.
- Mix and homogenize the liquid phase.
- Calculate the total weight of the lactose (total weight of the formulation minus the total weight of the solid active inputs).
- Incorporate the liquid phase to the lactose and homogenize it
- Mix the solid phase to this preparation and homogenize it
- Mold in bar container. As required, use sufficient quantity of ethanol at 77% (v/v) (equivalent to 70% (p/p)) or higher to achieve the molding point.
- Proceed with the extrusion. Dry, as required, at a temperature not higher than 50 °C and tamis.

Example.

Calcarea carb. 3 DH trit.
Calcarea phosph. 3 DH trit. } ãã . . . . . qsp 5%

China officinalis 3 CH
Avena sativa 3 CH } ãã . . . . . qsp 5%

Lactose . . . . . qsp 100g.

alcohol at 77% (v/v) (equivalent to 70% (p/p)) or higher . . . . . qs

Preparation:
- Total weight of the formulation = 100 g.
- Weight of each solid active input (2.5%) → 2.5 g.
- Total weight of the solid active inputs (5%) → 5 g.
- Mix and homogenize the solid phase → 2.5 g x 2 = 10 g.
- Volume of each liquid active input (2.5%) → 2.5 mL.
- Mix and homogenize the liquid phase → 2.5 mL x 2 = 5 mL.
- Total weight of the lactose (total weight of the formulations minus total weight of the solid active inputs) → 100 g – 5 g = 95 g.

This translation does not replace the portuguese version.

- Add the liquid phase to the lactose and homogenize it
- Then, add the solid phase to this preparation and homogenize it
- Mold in bar container. As required, use ethanol at 77% (v/v) (equivalent to 70% (p/p)) or higher to achieve the molding point.
- Proceed with the extrusion. Dry, as required, at a temperature not higher than 50 °C and tamis.

12.1.3.2.5 Single solid dose

1. *With a liquid active input:*

Technique.

- The single solid dose will be impregnated with two drops of active input.

Examples.

a) *Gelsemium* 30 CH . . . . 1 tablet
b) *Gelsemium* 30 CH . . . . 5 globules
c) *Gelsemium* 30 CH . . . . 1 paper
d) *Gelsemium* 30 CH . . . . 1 bar
e) *Gelsemium* 30 CH . . . . 1 flacon or 1 sachet

2. *With two or more liquid active inputs:*

Technique.

- Separately prepare the active inputs appearing in the formulation, in the desired potencies, in ethanol at 77% (v/v) (equivalent to 70% (p/p)) or higher.
- Mix these preparations in equal and sufficient parts and homogenize it
- Impregnate with two drops of the prepared mixture and let it dry at the temperature not higher than 50 °C.

a) *Gelsemium* 30 CH
Eupatorium perfoliatum 30 CH } ãã . . . qsp . . . 1 tablet
b) *Gelsemium* 30 CH
Eupatorium perfoliatum 30 CH } ãã . . . qsp . . . 5 globules
c) *Gelsemium* 30 CH
Eupatorium perfoliatum 30 CH } ãã . . . qsp . . . 1 paper, 1 sachet or 1 flacon
d) *Gelsemium* 30 CH
Eupatorium perfoliatum 30 CH } ãã . . . qsp . . . 1 bar

3. *With a solid active input:*

Examples.

a) *Calcarea carbonica* 3 CH trit . . . 1 tablet
Procedure: as described in *Tablets* **(12.1.2.2)**.
b) *Calcarea carbonica* 3 CH trit . . . 1 paper, 1 sachet or 1 flacon
Procedure: as described in *Powders* **(12.1.2.4)**.
c) *Calcarea carbonica* 3 CH trit . . . 1 bar
Procedure: as described in *Bars* **(12.1.2.5)**.

4. *With two or more solid active inputs:*

Technique.

- Prepare by trituration, separately, the active inputs appearing in the formulation, in the desired potencies.

This translation does not replace the portuguese version.

- Mix these preparations in equal and sufficient parts and homogenize it
- Mix this preparation in the proportion of 10% (p/p) as a minimum with lactose.

Examples.

a) *Calcarea carbonica* 3 CH trit.
Ferrum metallicum 3 CH trit. } ãã . . . qsp . . . 1 tablet

Procedure: prepare by impregnation as described in *Tablets* **(12.1.2.2)**.

b) *Calcarea carbonica* 3 CH trit.
Ferrum metallicum 3 CH trit. } ãã . . . qsp . . . 1 paper, 1 sachet or 1 flacon

Procedure: as described in *Powders* **(12.1.2.4)**.

c) *Calcarea carbonica* 3 CH trit.
Ferrum metallicum 3 CH trit. } ãã . . . qsp . . . 1 bar

Procedure: as described in *Bars* **(12.1.2.5)**.

12.2 PHARMACEUTICAL FORMS FOR EXTERNAL USE

12.2.1 LIQUID PHARMACEUTICAL FORMS

12.2.1.1 LINIMENTS

They are pharmaceutical preparations containing, in their composition, active(s) dissolved in oils, and they may be incorporated into alcoholic solutions or emulsions.

- **Inert input.** Alcoholic solutions, oils and emulsifiable bases.

Technique.

- Prepare the active input in the desired potency and incorporate it to the inert input in the proportion of 10% (p/v) or (v/v).
- When it is more than one active input, prepare them, separately, in the desired potencies. Mix them in equal parts and homogenize it Incorporate this preparation to the inert input in the proportion of 10% (p/v) or (v/v).

12.2.1.2 NASAL PREPARATIONS

They are the preparations assigned to the application in the nasal mucosa, being presented under the liquid or semi-solid forms.

- **Inert input.** Purified water, sodium chloride solution 0.9% (p/v), hydroglycerin solutions bases for semi-solid preparations.

Technique.

- Prepare the active input in the desired potency and incorporate it to the inert input in the proportion from 1% to 5% (p/v) or (v/v).
- When it is more than one active input, prepare them separately in the desired potencies, mix them in equal parts and homogenize it Incorporate this preparation to the inert input in the proportion from 1% to 5% (p/v) or (v/v).
- This preparation must present pH close to the physiological pH. Therefore, the use of buffers recommended at the literature is allowed. The use of preservatives is authorized.

12.2.1.3 OPHTHALMIC PREPARATIONS

They are the preparations assigned to the application in the ocular mucosa, being presented under the liquid or semi-solid forms.

- **Inert input.** Solution of sodium chloride 0.9% (p/v), purified water, cellulose derivatives and bases for semi-solid preparations.

Technique.

- Prepare the active input in the desired potency and incorporate it to the inert input in the proportion from 0.5% to 1% (p/v) or (v/v).
- When it is more than one active input, prepare them separately in the desired potencies, mix them in equal parts and homogenize it Incorporate this preparation to the inert input in the proportion from 0.5% to 1% (p/v) or (v/v).
- This preparation shall present pH close to the physiological pH and meet the requirements concerning tonicity and sterility. Therefore, isotoners, buffers and preservatives recommended at the literature are indicated.
- In the sterilization of the homeopathic ophthalmic preparations, the following methods will not be allowed: humid heat, dry heat, ionizing radiation and by sterilizing gas.
- In addition to these specifications, the homeopathic ophthalmic preparations must meet the general requirements for ophthalmic preparations.

12.2.1.4 OTOLOGICAL PREPARATIONS

They are the preparations assigned to the application in the auricular cavity, being presented under the liquid or semi-solid forms.

- **Inert input.** Alcoholic solutions, purified water, sodium chloride solution at 0.9% (p/v), hydroglycerin solutions bases for semi-solid preparations.

Technique.

- Prepare the active input in the desired potency and incorporate it to the inert input in the proportion of 10% (p/v) or (v/v).
- When it is more than one active input, prepare them, separately, in the desired potencies.
- Mix them in equal parts and homogenize it Incorporate this preparation to the inert input in the proportion of 10% (p/v) or (v/v). The use of preservatives is authorized.

12.2.2 SOLID PHARMACEUTICAL FORMS

12.2.2.1 MEDICINAL BANDAGE

They are proper substrates moisturized with active input(s) in the desired potency.

- **Substrates.** Sterilized cotton or sterilizied bandage.

Technique.

- Prepare the medicine containing one or more active inputs, in the desired potencies.
- Moisturize the substate with sufficient quantity of medicine.
- In case the product drying is required, it shall be made in a greenhouse with temperature not higher than 50 °C.

12.2.2.2 MEDICINAL POWDERS (MEDICINAL TALCS)

They are preparations resulting out of the incorporation of active input in the desired potency, to the properly pulverized inert input.

- **Inert input.** Amides, carbonates, stearates, oxides, silicates and others.

1. *With two or more liquid active inputs:*

Technique.
- Prepare the active input in the desired potency and incorporate it to the inert input in the proportion of 10% (v/p).
- When it is more than one active input, prepare them separately in the desired potencies, mix them in equal parts and homogenize it
- Impregnate the active input, in the proportion of 10% (v/p) to the inert input, homogenize and dry at the temperature not higher than 50 °C.

2. *With one or more solid active inputs:*

Technique.
- Prepare, by trituration, the active input in the desired potency and incorporate it to the inert input in the proportion of 10% (p/p).
- When it is more than one active input, prepare them separately, mix them in equal parts and homogenize it
- Add the active inputs in the proportion of 10% (p/p) to the inert input and homogenize it

3. *With solid and liquid active inputs:*

Technique.
- The active inputs of the solid phase will be prepared by tritutation, separately, in the desired potencies.
- Mix the active inputs of the solid phase, in equal and sufficient parts, in the proportions of the formulations and homogenize to compose this stage.
- The active inputs of the liquid phase will be prepared by tritutation, separately, in the desired potencies.
- Mix the active inputs of the liquid phase, in equal and sufficient parts, in the proportions of the formulations and homogenize to compose this stage.
- The sum of the active inputs must correspond to 10% of the final product.
- Calculate the total weight of the inert input to be added (total weight of the formulation minus the total weight of the solid active inputs). Incorporate the liquid phase to the inert input and homogenize it Then, incorporate the solid phase and homogenize it
- Dry at a temperature not higher than 50 °C.

12.2.2.3 SUPPOSITORIES

12.2.2.3.1 Rectal Suppositories

They are pharmaceutical preparations with proper format for rectal administration.
- **Inert input.** Cocoa butter, polyols and other bases for suppositories.

1. *With two or more liquid active inputs:*

Technique.
- Prepare the active input in the desired potency and incorporate it to the inert input in the proportion of 5% (v/p).
- When it is more than one active input, prepare them separately, mix them in equal parts and homogenize it
- Incorporate at a temperature not higher than 50 °C, the active input to the cast inert input, in the proportion of 5% (v/p) as a minimum and mold it properly.

2. *With one or more solid active inputs:*

Technique.
- Prepare, by trituration, the active input in the desired potency and incorporate it to the inert input in the proportion of 5% (p/p).

This translation does not replace the portuguese version.

- When it is more than one active input, prepare them separately, mix them in equal parts and homogenize it
- Incorporate at a temperature not higher than 50 °C, the active input to the cast inert input, in the proportion of 5% (p/p) as a minimum and mold it properly.

3. *With solid and liquid active inputs:*

Technique.

- The active inputs of the solid phase will be prepared by tritutation, separately, in the desired potencies.
- Mix the active inputs of the solid phase, in equal and sufficient parts, in the proportions of the formulations and homogenize to compose this stage.
- The active inputs of the liquid phase will be prepared by tritutation, separately, in the desired potencies.
- Mix the active inputs of the liquid phase, in equal and sufficient parts, in the proportions of the formulations and homogenize to compose this stage.
- The sum of the active inputs must correspond to 5%, as a minimum, of the final product.
- Incorporate at a temperature not higher than 50 °C, the active inputs to the cast inert input, in the proportion of 5% (p/p) as a minimum and mold it properly.

12.2.2.3.2 Vaginal suppositories (Ovules)

They are pharmaceutical preparations with proper format for vaginal administration.

- **Inert input.** Glycerine gelatin, cocoa butter, polyols and other bases for suppositories.

1. *With one or more liquid active inputs:*

Technique.

- Prepare the active input in the desired potency and incorporate it to the inert input in the proportion of 5% (v/p).
- When it is more than one active input, prepare them separately, mix them in equal parts and homogenize it
- Incorporate at a temperature not higher than 50 °C, the active input to the cast inert input, in the proportion of 5% (v/p) as a minimum and mold it properly.

2. *With one or more solid active inputs:*

Technique.

- The active inputs of the solid phase will be prepared by tritutation, separately, in the desired potencies.
- Mix the active inputs of the solid phase, in equal and sufficient parts, in the proportions of the formulations and homogenize to compose this stage.
- The active inputs of the liquid phase will be prepared by tritutation, separately, in the desired potencies.
- Mix the active inputs of the liquid phase, in equal and sufficient parts, in the proportions of the formulations and homogenize to compose this stage.
- The sum of the active inputs must correspond to 5%, as a minimum, of the final product.
- Incorporate at a temperature not higher than 50 °C, the active inputs to the cast inert input, in the proportion of 5% (p/p) as a minimum and mold it properly.

3. *With solid and liquid active inputs:*

Technique.

- The active inputs of the solid phase will be prepared by tritutation, separately, in the desired potencies.

- Mix the active inputs of the solid phase, in equal and sufficient parts, in the proportions of the formulations and homogenize to compose this stage.
- The active inputs of the liquid phase will be prepared by tritutation, separately, in the desired potencies.
- Mix the active inputs of the liquid phase, in equal and sufficient parts, in the proportions of the formulations and homogenize to compose this stage.
- The sum of the active inputs must correspond to 5%, as a minimum, of the final product.
- Incorporate at a temperature not higher than 50 °C, the active inputs to the cast inert input, in the proportion of 5% (p/p) as a minimum and mold it properly.

12.2.3 SEMI-SOLID PHARMACEUTICAL FORMS

12.2.3.1 **CREAMS**

They are emulsified preparations constituted by an aqueous phase, an oilu phase and an emulsive agent.

- **Inert input.** Emsulfiable or auto-emulsifiable bases.

1. *With one or more liquid active inputs:*

Technique.

- Prepare the active input in the desired potency.
- When it is more than one active input, prepare them separately, mix them in equal parts and homogenize it
- Incorporate at a temperature not higher than 50 °C, the active input, in the proportion of 10% (v/p) to the inert input and mold it properly.

2. *With one or more solid active inputs:*

Technique.

- Prepare by trituration the active input in the desired potency.
- When it is more than one active input, prepare them separately, mix them in equal parts and homogenize it
- Incorporate at a temperature not higher than 50 °C, the active input, in the proportion of 10% (p/p) to the inert input and homogenize it

3. *With solid and liquid active inputs:*

Technique.

- The active inputs of the solid phase will be prepared by tritutation, separately, in the desired potencies.
- Mix the active inputs of the solid phase, in equal and sufficient parts, in the proportions of the formulations and homogenize to compose this stage.
- The active inputs of the liquid phase will be prepared by tritutation, separately, in the desired potencies.
- Mix the active inputs of the liquid phase, in equal and sufficient parts, in the proportions of the formulations and homogenize to compose this stage.
- The sum of the active inputs must correspond to 10% of the final product.
- This temperature not higher than 50 °C, incorporate the liquid phase to the inert input and homogenize, then incorporate the solid phase and homogenize it

This translation does not replace the portuguese version.

12.2.3.2 GELS

They are colloidal dispersions, predominantly hydrophilic, constituted by a solid and a liquid phase, homogeneous in aspect.

- **Inert input.** Alginates, cellulose derivatives, carboxyvinyl polymers and other bases for gels.

1. *With two or more liquid active inputs:*

Technique.

- Prepare the active input in the desired potency.
- When it is more than one active input, prepare them separately, mix them in equal parts and homogenize it
- Incorporate at a temperature not higher than 50 °C, the active input, in the proportion of 10% (v/p) to the inert input and homogenize it

2. *With one or more solid active inputs:*

Technique.

- Prepare by trituration the active input in the desired potency.
- When it is more than one active input, prepare them separately, mix them in equal parts and homogenize it
- Incorporate at a temperature not higher than 50 °C, the active input to the inert input in the proportion of 10% (p/p) and homogenize it

3. *With solid and liquid active inputs:*

Technique.

- The active inputs of the solid phase will be prepared by tritutation, separately, in the desired potencies.
- Mix the active inputs of the solid phase, in equal and sufficient parts, in the proportions of the formulations and homogenize to compose this stage.
- The active inputs of the liquid phase will be prepared by tritutation, separately, in the desired potencies.
- Mix the active inputs of the liquid phase, in equal and sufficient parts, in the proportions of the formulations and homogenize to compose this stage.
- The sum of the active inputs must correspond to 10% of the final product.
- Incorporate, at a temperature not higher than 50 °C, the liquid phase to the inert input and homogenize it Then, incorporate the solid phase and homogenize it

12.2.3.3 GELS-CREAMS

They are preparations which are homogeneous in aspect presenting common characteristics with the gels and creams.

- **Inert input.** Emulsifiable or auto-emulsifiable bases, alginates, cellulose derivatives, carboxyvinyl polymers and other bases.

1. *With two or more liquid active inputs:*

Technique.

- Prepare the active input in the desired potency.
- When it is more than one active input, prepare them separately, mix them in equal parts and homogenize it
- Incorporate at a temperature not higher than 50 °C, the active input, in the proportion of 10% (v/p) to the inert input and homogenize it

2. *With one or more solid active inputs:*

Technique.
- Prepare by trituration the active input in the desired potency.
- When it is more than one active input, prepare them separately, mix them in equal parts and homogenize it
- Incorporate at a temperature not higher than 50 °C, the active input, in the proportion of 10% (p/p) to the inert input and homogenize it

3. *With solid and liquid active inputs:*

Technique.
- The active inputs of the solid phase will be prepared by tritutation, separately, in the desired potencies.
- Mix the active inputs of the solid phase, in equal and sufficient parts, in the proportions of the formulations and homogenize to compose this stage.
- The active inputs of the liquid phase will be prepared by tritutation, separately, in the desired potencies.
- Mix the active inputs of the liquid phase, in equal and sufficient parts, in the proportions of the formulations and homogenize to compose this stage.
- The sum of the active inputs must correspond to 10% of the final product.
- Incorporate, at a temperature not higher than 50 °C, the liquid phase to the inert input and homogenize it Then, incorporate the solid phase and homogenize it

12.2.3.4 POMADES

They are monophasic preparations which are oily in aspect or not.
- **Inert input.** Greasy substances, alginates, cellulose derivatives, carboxyvinyl polymers and other bases.

1. *With two or more liquid active inputs:*

Technique.
- Prepare the active input in the desired potency.
- When it is more than one active input, prepare them separately, mix them in equal parts and homogenize it
- Incorporate at a temperature not higher than 50 °C, the active input, in the proportion of 10% (v/p) to the inert input and homogenize it

2. *With one or more solid active inputs:*

Technique.
- Prepare by trituration the active input in the desired potency.
- When it is more than one active input, prepare them separately, mix them in equal parts and homogenize it
- Incorporate at a temperature not higher than 50 °C, the active input, in the proportion of 10% (p/p) to the inert input and homogenize it

3. *With solid and liquid active inputs:*

Technique.
- The active inputs of the solid phase will be prepared by tritutation, separately, in the desired potencies.
- Mix the active inputs of the solid phase, in equal and sufficient parts, in the proportions of the formulations and homogenize to compose this stage.
- The active inputs of the liquid phase will be prepared by tritutation, separately, in the desired potencies.

This translation does not replace the portuguese version.

- Mix the active inputs of the liquid phase, in equal and sufficient parts, in the proportions of the formulations and homogenize to compose this stage.
- The sum of the active inputs must correspond to 10% of the final product.
- Incorporate, at a temperature not higher than 50 °C, the liquid phase to the inert input and homogenize it Then, incorporate the solid phase and homogenize it

This translation does not replace the portuguese version.

This translation does not replace the portuguese version.

13. BIOTHERAPEUTICS AND ISOTHERAPEUTICS

13.1 CLASSIFICATION

13.1.1 BIOTHERAPEUTICS

They are medicinal preparations obtained from biological products, chemically defined: secretions, excretions, tissues, organs, products of microbial origin and allergens. These preparations may be pathological (nosodies) or non-pathological (sarcodies) in origin, prepared in accordance with the homeopathic pharmacotechnique**.**

The stock biotherapeuticals are products whose active input is consistuted by samples prepared and supplied by specialized laboratory.

13.1.2 ISOTHERAPEUTICALS

They are medicinal preparations obtained from inputs related to the patient's pathology/ sickness, prepared in accordance with the homeopathic pharmacotechnique, being classified as auto-isotherapeuticals and hetero-isotherapeuticals.

13.1.2.1 AUTO-ISOTHERAPEUTICALS

They are isotherapeuticals whose active inputs are obtained from the patients themselves (fragments of organs and tissues, blood, secretions, excretions, calculi, feces, urine, microbial cultures and others) and assigned only to this patient.

13.1.2.2 HETERO-ISOTHERAPEUTICALS

They are isotherapeuticals whose active inputs are external to the patients (allergens, food, cosmetics, medicines, toxines, dust, pollen, solvents and others), which, in any way, sensitizes it.

13.2 MINIMUM REQUIREMENTS FOR THE PREPARATION OF BIOTHERAPEUTICS AND ISOTHERAPEUTICS

Since it is mostly composed of materials contaminated with micro-organisms, possibly presenting any pathogenicity, the preparation of the biotherapeuticals and isotherapeuticals must meet the homeopathic techniques and be made at laboratory ensuring the biological safety, in accordance with the legislation in effect.

When the microbial inactivity is proved, the preparation may be performed in common area of homeopathic manipulation.

In the case of materials of microbial, animal or human origin, proper measures must be taken in order to reduce risks related to the presence of infectious agents in the homeopathic preparations. For this purpose, the preparation method must own one or more stages, showing the elimination or inactivation of the infectious agents in the matrix.

This translation does not replace the portuguese version.

13.2.1 COLLECTION

The collection must be made under the guidance of licensed professional, at proper location, purtuant to the legislation in force.

When it is a microbial material, the collection must be made in order to ensure the presence of the ethological agent, avoiding it to be contaminated with other undesired micro-organisms.

The most important aspects in the collection procedures are:
- Every sample of biological origin must be trated as if it is pathogenic.
- Comply with and follow the technical standards of individual safety and protection (PPE: personal protective equipment).
- Decontaminate the external part of the collection vessel, when it is a pathogenic material.
- Collect the material, whenever possible, before starting any treatment.
- The material used in the collection must be, as much as possible, disposable, being required for its disposal to apply the PGRSS - Waste Management and Health Services Program, in accordance with the collected material and other effective standards for the manipulator's safety. The resuable material must be decontaminated so that the biosafety is ensured.

13.2.2 START-UPS

Biotherapeuticals: follow the specific monograph. When it is inexistent, use **Table 1**.

Isotherapeuticals: use the most adequate technique to the material characteristics.

The preparation of hetero-isotherapeuticals, using substances or pharmaceutical specialties containing substances subject to the special control must be made from the establishment or arising out of the patients themselves, upon meeting the requirements of the specific legislation in effect. However, the preparation and dispensing of dynamizations equal to or higher than 6 CH or 12 DH, with matrices obtained from homeopathic industrial laboratories, do not need any Special Authorization issued by the competent health surveillance agency.

SCALES
- Centesimal, Decimal or Fifty Milesimal.

METHOD
- *Hahnemann's Method*, *Korsakov's Method* and *Continuous flow method*

The main start-ups for the preparation of biotherapeuticals and isotherapeuticals are: allergens, calculi (biliary, dental, renal, salivary and vesical), microbial cultures, sputum, feces, fragments of organs and tissues, hairs, environmental dust, pus, skin or nail scrapes, saliva, blood, secretions, excretions, fluids, blood serum and urine.

The inert inputs to be used for the collection and preparation of the biotherapeuticals and isotherapeuticals are: lactose, alcoholic solutions in several gradations, purified water and, exceptionally, glycerine solution and sodium chloride solution at 0.9% (p/v).

The selected inert input must be compatible with the nature of the start-up.

This translation does not replace the portuguese version.

The auto-isotherapeuticals may only be stocked in ethanol 77% (v/v) (equivalent to 70% (p/p) or higher and dispensed from 12 CH or 24 DH).

Table 1 - Guideline for the material collection to be used as an active input in the preparation of biotherapeuticals and isotherapeuticals.

Material nature	*Sterilized vessel for collection*	*Sterile vehicle for collection*
Allergens	vials, Petri dish or universal collector	glycerine solution, purified water, ethanol at 70% (v/v)
Calculi (biliary, dental, renal, salivary or vesical)	vial or unversal collector	
Microbial cultures	as per laboratorial	procedure as per procedure laboratorial
Sputum	universal collector	
Feces	universal collector	glycerine solution
Fragments of organs or tissues	universal collector	glycerine solution
Hairs	universal collector	
Environmental dust	universal collector	
Pus	culture tube with threaded cap	glycerine solution ethanol at 70% (v/v)
Skin or nails scrapes	Petri dish	
Saliva	universal collector	glycerine solution
Total venous blood	vial, without anticoagulant, with minimum quantity purified water capable of causing hemolysis	purified water of ethanol at 70% (v/v)
Secretions, excretions and fluids	universal collector, tube culture with threaded cap	of glycerine solution lactose ethanol at 70% (v/v)
Blood serum	vial	purified water ethanol at 70% (v/v)
Urine	universal collector	

This translation does not replace the portuguese version.

This translation does not replace the portuguese version.

14. LABELLING

It is the convenient identification directly applied over any vessel, casing, cartridge or any other packaging protector.
The homeopathic medicines shall meet the legislation in force on the labels, in addition to having, as a minimum, the following elements:

- Name of the establishment, Brazilian Registry of Legal Entities (CNPJ), address and telephone.
- Name of the technician in charge and the name of his/her registration in the Regional Pharmacy Council.

In addition to the requirements above, the label must contain, in te cases specified below, the following data:

Mother tincture

- Scientific name of the drug.
- Mother tincture in words or TM acronym or symbol.
- Pharmacopoeia used in the preparation.
- Date of manufacture, expiry date and batch.
- Status of the drug (dry or fresh).
- Used part.
- Alcoholic rate.
- Volume.

Other matrices.

- Scientific or homeopathic name.
- Potency, scale and method, followed by the word “Matrix”.
- Quantity.
- Date of manufacture, expiry date and batch.
- Solid inert input and/or alcoholic rate.

Magistral pharmaceutical forms for dispensing.

- Heompathic name.
- Potency, scale and method.
- Pharmaceutical form.
- Quantity.
- Date of manipulation.
- Expiry Date
- Posology.
- Internal or external use.
- Inert input and/or alcoholic rate.
- Patient’s name.
- Prescriber’s name.
- Conservation, as required.

Pharmacopoeic pharmaceutical forms for dispensing.

- Scientific or homeopathic name.
- Potency, scale and method.

This translation does not replace the portuguese version.

- Pharmaceutical form.
- Quantity.
- Date of manufacture, expiry date and batch.
- Internal or external use.
- Inert input and/or alcoholic rate.
- Conservation, as required.

This translation does not replace the portuguese version.

15. MONOGRAFIAS

ACIDUM ACETICUM 89
ACIDUM BENZOICUM 91
ACIDUM CARBOLICUM 93
ACIDUM FORMICUM 95
ACIDUM LACTICUM 97
ACIDUM NITRICUM 99
ACIDUM OXALICUM 101
ACIDUM PHOSPHORICUM 103
ACIDUM SALICYLICUM 105
ACIDUM SULPHURICUM 107
ADRENALINUM 109
AESCULUS HIPPOCASTANUM 111
PURIFIED WATER 115
ALCOHOL 117
ALLIUM CEPA 119
ALUMEN 121
AMMONIUM CARBONICUM 123
AMMONIUM MURIATICUM 125
AMMONIUM PHOSPHORICUM 127
ANACARDIUM ORIENTALE 128
ANILINUM 130
APIS MELLIFICA 132
ARGENTUM METALLICUM 134
ARGENTUM NITRICUM 136
ARNICA MONTANA 138
AVENA SATIVA 141
BARYTA CARBONICA 143
BARYTA IODATA 145
BARYTA MURIATICA 147
BELLADONNA 149
BORAX 154
BRYONIA ALBA 156
CALCAREA CARBONICA 158
CALCAREA MURIATICA 160
CALCAREA PHOSPHORICA 162
CALCAREA SULPHURICA 164
CALENDULA OFFICINALIS 166
CARDUUS MARIANUS 168
CHAMOMILLA 170
CHELIDONIUM 172
CUPRUM METALLICUM 174
CYCLAMEN EUROPAEUM 176
DULCAMARA 178
ECHINACEA ANGUSTIFOLIA 181
ETHYLICUM 183
FERRUM METALLICUM 186

This translation does not replace the portuguese version.

FERRUM SULPHURICUM 188
GELSEMIUM. 190
GINKGO BILOBA. 193
GLYCEROL 195
INERT GLOBULES 197
GLONOINUM 198
GUAIACUM OFFICINALE 200
HYDRASTIS CANADENSIS 203
HYOSCYAMUS NIGER 206
HYPERICUM PERFORATUM 209
IGNATIA AMARA. 211
IODIUM 213
IPECACUANHA 214
KALI BICHROMICUM. 217
KALI BROMATUM. 219
KALI IODATUM 221
KALI MURIATICUM 222
KALI PHOSPHORICUM. 224
LACTOSE. 226
LOBELIA INFLATA. 228
LYCOPODIUM CLAVATUM 230
MAGNESIA CARBONICA 232
MAGNESIA MURIATICA. 234
MAGNESIA PHOSPHORICA. 236
MERCURIUS SULPHURATUS RUBER 238
NATRUM CARBONICUM 240
NATRUM MURIATICUM. 242
NATRUM SULPHURICUM 244
NUX VOMICA. 246
PAEONIA OFFICINALIS 249
PARREIRA BRAVA 251
PHYTOLACCA DECANDRA. 253
RHUS TOXICODENDRON 255
RICINUS COMMUNIS 257
RUTA GRAVEOLENS. 259
STAPHYSAGRIA. 261
SULPHUR 264
TARAXACUM OFFICINALE. 266
THUYA OCCIDENTALIS 269

This translation does not replace the portuguese version.

ACIDUM ACETICUM

- $C_2H_4O_2$; 60.06 [*64-19-7*]
- It contains, as a minimum, 99.4% of $C_2H_4O_2$.

HOMEOPATHIC SYNONYMY
- Aceti acidum, Acetic acidum.

CHEMICAL NAME
- Ethanoic acid, glacial acetic acid, acetic acid.

DESCRIPTION
- **Physical-chemical characteristics.** Limpid, volatile, colorless, acidic odor, penetrating, spicy, irritating, acidic flavor liquid. It solidifies at 16.7 °C as a crystaline mass, in thin, hexagonal, colorless and transparent splinters. Its vapors are easily flammable, it burns producing a bluish flame.
- **Solubility.** Miscible in every proportion with water, ethanol, ethyl ether, acetone, chloroform, benzene and glycerine.
- **Incompatibilities.** Alkalis, alkaline carbonates, iron salts, glycosides, some oxides, phosphates and lactose.

Physical-chemical constants.
- *Relative density* **(5.2.5) FB 5**: 1.05 g/mL, at 25 °C.
- *Boiling point* **(5.2.3) FB 5**: 118 °C.

IDENTIFICATION

A. In any test tube, heat 5 mL of the sample with equal quantity of ethanol and drops of concentrated sulfuric acid. There is the formation of ethyl acetate, in characteristic odor.

B. In any test tube, place 2 mL of the sample. Add drops of sodium hydroxide solution at 10% (p/v) up to neutralization. Then, add drops of the ferric chloride solution at 1% (p/v). Dark red color is developed, which fades away by adding drops of the hydrochloric acid solution at 1% (v/v).

PURITY TESTING
- **Hydrochloric acid.** Dilute 1 mL of the sample into 20 mL of purified water. Add drops of the silver nitrate solution at 1% (p/v). Precipitation or turbidity must not be observed.
- **Sulfuric acid.** Dilute 1 mL of the sample into 20 mL of purified water. Add drops of the barium chloride solution at 1% (p/v). Precipitation or turbidity must not be observed.
- **Arsenic (5.3.2.5) FB 5.** Proceed as described in *Limit testing for arsenic*. As a maximum 0.0002% (2 ppm).
- **Chlorides (5.3.2.1) FB 5.** Dissolve 5 mL of the sample into 15 mL of purified water. Proceed as described in Limit testing for chlorides. As a maximum 0.002% (20 ppm).
- **Heavy metals (5.3.2.3) FB 5.** Use *Method I*. Evaporate 5 mL of the sample into a porcelain capsule until it dries, in boiling bain-marie. Add 25 mL of purified water to the obtained residue. Proceed as described in Limit testing for heavy metals. As a maximum 0.001% (10 ppm).
- **Non-volatile substances.** In a previously weighed porcelain capsule, add 20g of the sample. Evaportate until it dries in boilding bain-marie. Dry until a constant weight in the vacuum

This translation does not replace the portuguese version.

desiccator containing desiccant. The residue must not be higher than 0.01% (p/p) in relation to the initial sample.

DOSAGE

- In an Erlenmeyer flask containing 50 mL of purified water, add 5 g of the accurately weighed sample of 1 mg. Entitle with sodium hydroxide *M* SV, using the phneolftalein SI as an indicator.
- Each mL of sodium hydroxide *M* SV is equivalent to 0.060 g of $C_2H_4O_2$.

PACKAGING AND STORAGE

- In a neutral, amber, tight closed glass vessel, protected from light and heat.

DERIVATIVE FORM

- **Start-up.** Glacial acetic acid ($C_2H_4O_2$).
- **Inert input.** Use purified water up to 3 CH or 6 DH and, for others, follow the general rule of preparation of derivative pharmaceutical forms.
- **Method.** *Hahnemann's Method* **(11.1),** *Korsakov's Method* **(11.2),** *Continuous flow method* **(11.3).**
- **Dispensing:** From 1 CH to 3 CH or from 3 DH to 6 DH, prepare in purified water (extemporaneous preparation). From 4 CH or 7 DH, follow the general rule of dispensing.
- **Packaging and Storage.** In a neutral, amber, tight closed glass vessel, protected from light and heat.

This translation does not replace the portuguese version.

ACIDUM BENZOICUM

- $C_7H_6O_2$; 122,12 [*65-85-0*]
- It contains, as a minimum, 99.5% and, as a maximum, 100.5% of $C_7H_6O_2$, in relation to the anhydrous substance.

HOMEOPATHIC SYNONYMY
- Benzoic acid.

CHEMICAL NAME
- Benzoic acid.

DESCRIPTION
- **Physical characteristics.** White powder, crystaline or colorless crystals, odorless or with slight odor very characteristic.
- **Solubility.** Slightly soluble in water, soluble in boiling water, easily soluble in ethanol, ethyl ether and fatty acids.

Physical-chemical constants.
- *Melting range* **(5.2.2) FB 5**: 121 °C to 124 °C.

IDENTIFICATION

A. Prepare a saturated solution of benzoic acid in water and filter twice. At one portion of the filtered solution, add the SR ferric chloride. There is the formation of an orange precipitation. At another 10 mL portion of the filtered solution, add 1 mL of sulfuric acid 3 *M* and cool the mixture. There is the formation of a white precipitation, soluble in ethyl ether, in approximately 10 minutes.

B. Dissolve 5 g of the sample into 100 mL of ethanol. It responds to the benzoate ion reactions **(5.3.1.1) FB 5**.

PURITY TESTING
- **Solution aspect.** Dissolve 5 g of the sample into 100 mL of ethanol. The obtained solution is limpid **(5.2.25) FB 5**.
- **Oxidizable substances.** Dissolve 2 g of the sample into 10 mL of boiling water, cool and filter it. Add to the filtered solution 1 mL of sulfuric acid at 5% (v/v) and 0.2 mL of potassium permanganate at 0.02 *M*. A pink coloring is formed for, at least, 5 minutes.
- **Carbonizable substances.** Dissolve 0.5 g of the sample into 5 mL of sulfuric acid SR. After 5 minutes, the solution is not more intensely colorful than the solution prepared by diluting 12.5 mL of the *Standard solution with the color SC H* **(5.2.12) FB 5** for 100 mL with hydrochloric acid SR.
- **Halogenated compounds and halides.** Prepare the solutions described as follows.

Note: *the entire laboratory glassware must be clear of chlorides. One way of obtaining it is to complete the laboratory glassware with a nitric acid solution at 50% (p/v) and leave it in ultrasound bath for one night. On the next day, wash the laboratory glassware with water and keep it filled with water. Having a reserved laboratory glassware for the performance of this test is recommended.*

This translation does not replace the portuguese version.

- *Solution (1)*: dissolve 6.7 g os the sample into a 40 mL mixture of sodium hydroxide 0.1 *M* and 50 mL of ethanol and complete the volume up to 100 mL with water. In 10 mL of this solution, add 7.5 mL of sodium hydroxide solution SR, 0.125 g of nickel-aluminum alloy and heat in bain-marie for 10 minutes. Let it cool at room temperature, filter and wash with three portions, 3 mL each, of ethanol. Wash it with 25 mL of water.
- *Solution (2)*: prepare this solution in a similar manner as the *Solution (1),* however, not using the sample.
- *Solution (3)*: standard chloride solution (8 ppm Cl).

In four 25 mL volumetric flasks, add separately 10 mL of the *Solution (1),* 10 mL of the *Solution (2),* 10 mL of the *Solution (3)* and 10 mL of water. In every vial, add 5 mL of amoniacal ferric sulfate SR1, 2mL of the nitric acid SR and 5 mL of the mercury thiocyanate SR. Complete the volume of each vial for 25 mL with water. Let it rest in bain-marie at 20 °C for 15 minutes. Proceed as described in *Absorption spectrophotometry in visible* **(5.2.14) FB 5**. Measure the absorbance of the *Solution (1)* at 460 nm, using the *Solution (2)* for zero adjustment. Measure the absorbance of the *Solution (3)* at 460 nm, using the obtained solution with 10 mL of water for zero adjustment. The absorbance of the *Solution (1)* is not higher than the absorbance of the *Solution (3)* (300 ppm).

- **Heavy metals (5.3.2.3) FB 5.** Use *Method III*. Dissolve 5 g of the sample into 100 mL of ethanol. Prepare the standard solution by using ethanol as a solvent. As a maximum 0.001% (10 ppm).
- **Water (5.2.20.1) FB 5.** Dissolve the sample in a mixture of methanol and pyridine (1:2). As a maximum 0.7%.
- **Sulfated ashes (5.2.10) FB 5.** Determine in 1 g of the sample. As a maximum 0.05%.

DOSAGE

- Weight, exactly, about 200 mg of the sample and dissolve into 20 mL of ethanol. Entitle the sodium hydroxide 0.1 *M* SV, by using phenol red SI until violet color is formed, corresponding to the final point of the entitlement. Each mL of the sodium hydroxide 0.1 *M* SV is equivalent to
- 12.212 mg of $C_7H_6O_2$.

PACKAGING AND STORAGE

- In tight closed and opaque vessels.

DERIVATIVE FORM

- **Start-up.** Benzoic Acid ($C_7H_6O_2$).
- **Inert input.** Use lactose up to 3 CH or 6 DH and, for others, follow the general rule of preparation of derivative pharmaceutical forms.
- **Method.** *Hahnemann's Method* **(11.1),** *Korsakov's Method* **(11.2),** *Continuous flow method* **(11.3).**
- **Dispensing:** From 1 CH or 2 DH, follow the general rule of dispensing.
- **Packaging and Storage.** In a neutral, amber, tight closed vessel.

This translation does not replace the portuguese version.

ACIDUM CARBOLICUM

- C_6H_6O; 94,11 [*108-95-2*]
- It contains, as a minimum, 99.0% and, as a maximum, 100.5% of C6H6O, in relation to the anhydrous substance.

HOMEOPATHIC SYNONYMY
- Phenolum, Phenol, Carbolicum acidum, Phenolum purum.

CHEMICAL NAME
- Phenol.

DESCRIPTION
- **Physical characteristics.** Colorless acicular crystals or white crystalline mass, characteristic odor corrosive, irritating for mucosas and skin, deliquescent. It gets dark when it is exposed to air and light.
- **Solubility.** Soluble in water, very soluble in ethanol, ethyl ether, chloroform, glycerol and oils fixed and volatile, insoluble in petroleum ether.

Physical-chemical constants.
- *Freezing temperature* **(5.2.4) FB 5**: as a minimum, 39 °C.

IDENTIFICATION
A. At 5 mL of an aqueous solution of the sample at 2% (p/v), add one drop of the aqueous solution of ferric chloride at 5% (p/v). The violet color is dissolved. Add 10 mL of ethanol at 90% (v/v). A the color becomes yellow.
B. Add bromine water ST at an aqueous solution of the sample at 1% (p/v). A white precipitation is produced, which is immediately dissolved, but it is permanent after adding excessive reagents.

PURITY TESTING
- **Solution aspect.** The 1 g solution of the sample in 15 mL of water is limpid **(5.2.25) FB 5**.
- **Acidity.** At 5 mL of a 1 g solution of the sample in 15 mL of water, add one drop of methyl orange SI. The yellow color is produced.
- **Water (5.2.20.1) FB 5.** As a maximum 0.5%.
- **Residue by evaporation.** Weigh exactly about 5 g of the sample, evaportate in bain-marie and dry at 105 °C for 1 hour. The residue mass must not be higher than 2.5 mg.

DOSAGE
- Weigh exactly about 0.2 g of the sample, dissolve into water and complete the volume for 100 mL with the same solvent. Transfer 25 mL of the solution into an Erlenmeyer flask with a cap and add 50 mL of bromine 0.05 *M* SV and 5 mL of hydrochloric acid. Cap, stir occasionally for 20 minutes and protect from light for 15 minutes. Add 5 mL of solution of potassium iodide at 20% (p/v) and stir smoothly. Entitle with sodium thiosulfate 0.1 *M* SV. Add mL of the amide solution SI and 10 mL of chloroform when the solution color remains slightly yellow. Continue the entitlement with vigorous stirring until the color blue fades away. Perform the testing in white and make the required corrections. Each mL of bromine 0.05 *M* SV is equivalent to 1.569 mg of C_6H_6O.

This translation does not replace the portuguese version.

PACKAGING AND STORAGE

- In a neutral, amber, hermetically closed glass vessel, protected from light and heat.

DERIVATIVE FORM

- **Start-up.** Monohydroxibenzene (C_6H_6O).
- **Inert input.** Use ethanol 70% up to 3 CH or 6 DH and, for others, follow the general rule of preparation of derivative pharmaceutical forms.
- **Method.** *Hahnemann's Method* (**11.1**), **Korsakov's Method** *(***11.2***), Continuous flow method* **(11.3)**.
- **Dispensing:** From 3 CH or 6 DH, follow the general rule of dispensing.
- **Packaging and Storage.** In a neutral, amber, tight closed glass vessel, protected from light and heat.

This translation does not replace the portuguese version.

ACIDUM FORMICUM

- H_2CO_2; 46.03 [*64-18-6*]
- It contains, as a minimum, 98% of H_2CO_2.

HOMEOPATHIC SYNONYMY
- Formic acid.

CHEMICAL NAME
- Methanoic acid, formic acid.

DESCRIPTION
- **Physical characteristics.** Limpid, colorless, punging odor, acre flavor and intensely corrosive liquid.
- **Solubility.** Miscible in every proportion with water, ethanol, ethyl ether and glycerol. Little soluble in benzene, toluene and xylene.
- **Incompatibilities.** Alkalis and alkaline carbonates in general, soluble lead salts, soluble silver salts.

Physical-chemical constants.
- *Relative density* **(5.2.5) FB 5**: Close to 1.22 g/mL at 25 °C.
- *Boiling point* **(5.2.3) FB 5**: 100.8 °C.

IDENTIFICATION
A. Dilute the small quantity of anhydrous formic acid with sufficient quantity of purified water. The solution is strongly acidic.
B. At 1 mL of anhydrous formic acid, add 2 mL of silver nitrate solution at 1% (p/v). Heat until it boils. The formation of black precipitation is observed, and it may reach the formation of silver mirror.
C. At 0.5 mL of anhydrous formic acid, add 2 mL of lead acetate SR. The formation of white precipitation is observed.

PURITY TESTING
- **Solution aspect.** At 2 mL of anhydrous formic acid, add 8 mL of purified water. The solution is limpid **(5.2.25) FB 5** and colorless **(5.2.12) FB 5**.
- **Arsenic (5.3.2.5) FB 5.** 1 g of anhydrous formic acid must meet the *Limit testing for arsenic*. As a maximum 0.0001% (1 ppm).
- **Chlorides (5.3.2.1) FB 5.** Dissolve 2.5 g of anhydrous formic acid into 15 mL of purified water. Proceed as described in *Limit testing for chlorides*. As a maximum 0.002% (20 ppm).
- **Heavy metals (5.3.2.3) FB 5.** Use *Method I*. Dissolve the resulted obtained in *Loss by desiccation* in 1 mL of hydrochloric acid. Complete the volume with 20 mL of purified water. At 1 mL of this solution, add 11 mL of purified water. Proceed as described in *Limit testing for heavy metals*, comparing the solution prepared with a diluted standard lead solution (1 ppm Pb). As a maximum 0.001% (10 ppm).
- **Sulfates (5.3.2.2) FB 5.** At 5 g of anhydrous formic acid, add 0.05 g of anhydrous sodium carbonate. Evaporte until dryness in exhaust hood. Dissolve the residue into 1 mL of diluted hydrochloric acid and complete the volume for 25 mL with purified water. 15 mL of the solution must meet the *Limit testing for sulfates*. As a maximum 0.005% (50 ppm).

This translation does not replace the portuguese version.

- **Loss by desiccation (5.2.9) FB 5.** Evaporate in bain-marie 20 g of the sample and desiccate between 100 °C and 105 °C until the weight is constant. The residue must not exceed 0.05% (p/p).

DOSAGE
- In an Erlenmeyer flask with ground glass cap, containing 10 mL of purified water, add 1 mL of anhydrous formic acid. Add, then, 50 mL of purified water. Entitle sodium hydroxide *M* SV deploying as indicator 0.5 mL of phenolftalein SI until it becomes rosaceous in color. each mL of
- the sodium hydroxide *M* SV is equivalent to 0.046 g of H_2CO_2.

PACKAGING AND STORAGE
- In a neutral, tight closed glass vessels, protected from light and heat.

DERIVATIVE FORM
- **Start-up.** Anhydrous formic acid (H_2CO_2).
- **Inert input.** Use purified water up to 3 CH or 6 DH and, for others, follow the general rule of preparation of derivative pharmaceutical forms.
- **Method.** *Hahnemann's Method* **(11.1),** *Korsakov's Method* **(11.2),** *Continuous flow method* **(11.3).**
- **Dispensing:** From 2 CH to 3 CH or from 3 DH to 6 DH, prepare in purified water (extemporaneous preparation). From 4 CH or 7 DH, follow the general rule of dispensing.
- **Packaging and Storage.** In a neutral, amber, tight closed glass vessel, protected from light and heat.

This translation does not replace the portuguese version.

ACIDUM LACTICUM

- $C_3H_6O_3$; 90.08 [*50-21-5*]
- Mixture of lactic acid and its condensation products, such as lactoil -lactic acid, and polylactic acids and water. The balance between lactic acid and the polylactic acids depends on the concentration and temperature. Lactic acid is normally a racemate ((*RS*)-lactic acid), but the isomer *S* (+) may predominate. It contains, as a minimum, 88.0% and, as a maximum, 92.0% of $C_3H_6O_3$.

HOMEOPATHIC SYNONYMY
- Lactis acidum.

CHEMICAL NAME
- Lactic acid, 2-hydroxypropanoic acid.

DESCRIPTION
- **Physical characteristics.** Colorless or slightly yellow viscous liquid.
- **Solubility.** Miscible in water, ethanol and ethyl ether.

Physical-chemical constants.
- *Rotatory power* **(5.2.8) FB 5**: -0.05° to +0.05°, for the racemic lactic acid.

IDENTIFICATION
A. Dissolve 1 g of the sample into water. The solution is strongly acidic (pH lower than 4.0).
B. It responds to the lactate ion reactions (5.3.1.1) FB 5.

PURITY TESTING
- **Solution aspect.** Dissolve 5 g of the sample into 42 mL of sodium hydroxide *M* and dilute for 50 mL with water. The obtained solution is not more colorful than *Standard solution in color SC F* **(5.2.12) FB 5**.
- **Sugars and other reducing substances.** At 10 L of hot alkaline cupric tartarate SR add five drops of the sample. No red precipitation is produced.
- **Easily carbonizable substances.** Wash a test tube with sulfuric acid and let it run off for 10 minutes. Add to the test tube 5 mL of sulfuric acid and, carefully, add 5 mL of the sample, in order not to mix the liquids. Maintain the tube at a temperature of 15 °C. After 15 minutes, no dark color is developed in the interface between both acids.
- **Substances insoluble in ethyl ether.** Dissolve 1 g of the sample into 25 mL of ethyl ether. The solution is not more opalescent than the solvent used for the test.
- **Oxalic, citric and phosphoric acids.** At 5 mL of the obtained solution in *Solution aspect* add ammonia SR until the pH is weakly alkaline (between 8 and 10). Add 1 mL of calcium chloride SR. Heat in bain-marie for 5 minutes. Any opalescence in the solution, before or after being heated, is not more intense than the mixture of 1 mL of water and 5 mL of the solution obtained in *Solution aspect*.
- **Calcium (5.3.2.7) FB 5.** Dilute 5 mL of the solution obtained in *Solution aspect* for 15 mL with water and proceed as described in *Limit testing for calcium*. As a maximum 0.02% (200 ppm).
- **Chlorides (5.3.2.1) FB 5.** At 10 mL of the sample solution at 1% (p/v), acidified with nitric acid, add some drops of silver nitrate 0.1 *M*. No opalescence is immediately produced.

This translation does not replace the portuguese version.

- **Heavy metals (5.3.2.3) FB 5.** Use *Method III*. As a maximum 0.001% (10 ppm).
- **Sulfates (5.3.2.2) FB 5.** At 10 mL of the sample solution at 1% (p/v) add two drops of chloridric acid and 1 mL of barium chloride SR. No turbidity is produced.
- **Sulfated ashes (5.2.10) FB 5.** Determine in 1 g of the sample. As a maximum 0.1%.

DOSAGE
- Transfer, exactly, about 1 g of the sample into a capped vial, add 10 mL of water and 20 mL of sodium hydroxide *M*. Close the vial and let it rest for 30 minutes. Add 0.5 mL of phenolftalein SI and entitle with hydrochloric acid *M* SV until the pink color fades away. Each mL of sodium
- hydroxide *M* is equivalent to 90.080 mg of $C_3H_6O_3$.

PACKAGING AND STORAGE
- In a neutral, amber, hermetically closed vessel.

DERIVATIVE FORM
- **Start-up.** Lactic acid ($C_3H_6O_3$).
- **Inert input.** Hydroalcoholic solution in different gradations.
- **Method.** *Hahnemann's Method* **(11.1),** *Korsakov's Method* **(11.2),** *Continuous flow method* **(11.3).**
- **Dispensing:** From 2 DH or 1 CH.
- **Packaging and Storage.** In a neutral, amber, tight closed vessel.

This translation does not replace the portuguese version.

ACIDUM NITRICUM

- HNO_3; 63.01 [*7697-37-2*]
- It contains, as a minimum, 65% and, as a maximum, 69% of HNO3.

HOMEOPATHIC SYNONYMY
- Acidum azoticum, Acidum nitri, Acidum nitricum depuratum, Nitri acidi, Nitricum acidum.

CHEMICAL NAME
- Nitric acid.

DESCRIPTION
- **Physical characteristics.** Colorless or slightly yellow liquid, with characteristic odor, penetrating, strong and irritating.
- **Solubility.** Soluble in water and ethanol in every proportion.
- **Incompatibilities.** Alkalis, alkaline salts, organic matters in general, phenol and glycerol.

Physical-chemical constants.
- *Relative density* **(5.2.5) FB 5**: 1.41 g/mL at 20 °C.
- *Boiling point* **(5.2.3) FB 5**: 122 °C.

IDENTIFICATION
- Transer into a test tube, 1 mL of the sample, add 3 mL of sulfuric acid and, carefully, through the tube wall, add 1 mL of ferrous sulfate *M*. A brown ring is developed in the interface of the liquids.

PURITY TESTING
- **Arsenic (5.3.2.5) FB 5.** At 15 mL of the sample, add 5 mL of sulfuric acid and evaportate until the white fumes fade away. Add 1 mL of the hydroxylamine chloridrate solution to the residue at 10% (p/v) and dilute with purified water for 2 mL. Proceed as described in *Limit testing for arsenic*. As a maximum 0.1 ppm.
- **Sulfates.** Add 10 mg of sodium carbonate to 28 mL of the sample. Evaporate until dryness; dissolve the residue with a mixture of 4 mL of purified water and 1 mL of hydrochloric acid SR and complete the volume for 10 mL. Add 1 mL of the barium chloride solution at 1% (p/v). After 10 minutes of the addition of reagents, the turbidity produced must not be higher than that obtained with 40 µL of sulfuric acid 0.01 *M*.

DOSAGE
- Transfer, through 25 mL volumetric pipette of the sample into the 250 mL volumetric flask, complete the volume with purified water and homogenize it. Transfer into an Erlenmeyer flask, 25 mL of the diluted sample solution, add approximately 50 mL of purified water, add 0.1 mL of methyl red SI and entitle with sodium hydroxide *M* SV. Each mL of the sodium hydroxide *M* SV is equivalent to 0.063 g of HNO_3.

PACKAGING AND STORAGE
- In a neutral, amber, tight closed glass vessel, protected from light and heat.

This translation does not replace the portuguese version.

DERIVATIVE FORM

- **Start-up.** Nitric acid (HNO_3).
- **Inert input.** Use purified water up to 3 CH or 6 DH and, for others, follow the general rule of preparation of derivative pharmaceutical forms.
- **Method.** *Hahnemann's Method* **(11.1),** *Korsakov's Method* **(11.2),** *Continuous flow method* **(11.3).**
- **Dispensing:** At 3 CH or 6 DH, prepare in purified water (extemporaneous preparation). From 4 CH or 7 DH, follow the general rule of dispensing.
- **Packaging and Storage.** In a neutral, amber, tight closed vessel.

This translation does not replace the portuguese version.

ACIDUM OXALICUM

- $C_2H_2O_4.2H_2O$; 126.07 [*144-62-7*]
- It contains, as a minimum, 99.5% and, as a maximum, 100.5%, of $C_2H_2O_4$.

HOMEOPATHIC SYNONYMY
- Oxalii acidum.

CHEMICAL NAME
- Oxalic acid.

DESCRIPTION
- **Physical characteristics.** Transparent and colorless crystals.
- **Solubility.** Easily soluble in water and ethanol, slightly soluble in glycerine. Insoluble in chloroform, benzene, petroleum ether.
- **Incompatibilities.** Soluble calcium salts, iron salts, gold salts, silver salts, magnesium salts, permanganates, cynadies and other oxidizers, sulfuric acid and mercuric chloride.
- **Physical-chemical constant.**
- *Melting range* **(5.2.2) FB 5:** 101 °C to 102 °C.

IDENTIFICATION

A. In a porcelain capsule, add at 50 mg of the oxalic acid sample, 10 mg of resorcinol and one drop of glycerine, mix until the resorcinal is dissolved. Add five drops of sulfuric acid without stirring. The red-violet, towards blue, is dissolved. This reaction allows characterizing 0.0063 mg of oxalic acid in the sample under analysis.

B. Join equal parts of oxalic acid, diphenylamine chloridrate and benzoic acid. Heat smoothly until it melts. The color blue is developed. Add ethanol until it dissolves. Ethanol may develop the color blue as well. It allows characterizing 10 mg of oxalic acid in the sample under analysis.

C. A solution containing 100 mg of oxalic acid in 2 mL of purified water and 1 mL of sodium hydroxide 6 *M* produces, through agitation, a crystalline precipitation.

D. Place, in the depression of the porcelain plate, five drops of hydrochloric acid at 50% (v/v) and zinc granules and one drop of the concentrated solution of oxalic acid. After 5 minutes, remove the excessive non-attacked zinc, add one drop of phenylhydrazine solution at 1% (p/v) recently prepared. Lead to the greenhouse at 110 °C for 5 minutes. Let it cool down. Add one drop of concentrated hydrochloric acid and one drop of hydrogen peroxide solution at 3% (v/v). The color varying from rosaceous to pink is dissolved after 3 to 4 minutes.

E. In a test microtube, place the mixture of equal parts of oxalic acid and diphenylamine. Lead to melt in Bunsen burner's flame. Let it cool down. Disolve the cast mixture with one drop of ethanol. The color blue is developed.

PURITY TESTING
- **Solution aspect.** Dissolve 1 g of the sample into 15 mL of purified water. The solution must be limpid **(5.2.25) FB 5** and colorless **(5.2.12) FB 5**.
- **Chlorides (5.3.2.1) FB 5.** Dissolve 1 g of the sample into 15 mL of purified water. Proceed as described in Limit testing for chlorides. As a maximum 0.002% (20 ppm).
- **Heavy metals (5.3.2.3) FB 5.** Use *Method I*. To the residue obtained in *Sulfated ashes* add 3 mL of hydrochloric acid 6 *M* and evaporate to dryness. Dissolve the residue obtained in 2 mL

of hydrochloric acid 0.1 *M* and dilute to 20 mL with purified water. Use 12 mL and proceed as described in Limit testing for heavy metals. As a maximum 0.002% (20 ppm).

- **Iron (5.3.2.4) FB 5.** Use 5 mL of the aqueous solution of the sample prepared in the determination of *Heavy metals* and proceed as described in *Limit testing for iron*. As a maximum 0.0005% (5 ppm).
- **Easily carbonizable substances.** At 1 g of the sample, add 10 mL of concentrated sulfuric acid, heat carefully until the first white fumes fade away. After cooling down, the solution must not be more strongly colorful than the *Standard solution* described as follows.
  - *Standard solution*: mix 0.15 mL of anhydrous ferric chloride at 4.51% (p/v) with 0.1 mL of anhydrous cobaltous chloride at 6.5% (p/v) and 9.75 mL of hydrochloric acid at 1% (p/v).
- **Sulfated ashes (5.2.10) FB 5.** Determine in 10 g of the sample. As a maximum 0.1%.

DOSAGE

Deploy one of the methods described as follows.

A. Dissolve 120 mg of the sample in purified water. Entitled with sodium hydroxide 0.1 *M* SV, deploying as phenolftalein indicator SI. Each mL of sodium hydroxide 0.1 *M* SV is equivalent to 6.305 mg of $C_2H_2O_4.2H_2O$.

B. At 150 mg of the sample, add 30 mL of purified water and 10 mL of sulfuric acid at 70% (p/v). Entitle the temperature between 60 °C and 70 °C with potassium permanganate 0.02 *M* SV. Each consumed mL of potassium permanganate 0.02 *M* SV is equivalent to 6.305 mg de $C_2H_2O_4.2H_2O$.

PACKAGING AND STORAGE

- In a neutral, amber, hermetically closed vessel.

DERIVATIVE FORM

- **Start-up.** Oxalic acid ($C_2H_2O_4.2H_2O$).
- **Inert input.** Hydroalcoholic solution in different gradations.
- **Method.** *Hahnemann's Method* **(11.1),** *Korsakov's Method* **(11.2),** *Continuous flow method* **(11.3).**
- **Dispensing:** From 4 DH and 2 CH.
- **Packaging and Storage.** In a neutral, amber, tight closed vessel.

This translation does not replace the portuguese version.

ACIDUM PHOSPHORICUM

- H_3PO_4; 98.00 [*7664-38-2*]
- It contains, as a minimum, 85% and, as a maximum, 90% of H_3PO_4.

HOMEOPATHIC SYNONYMY
- Phosphoric acidi, Ortophosphoric acid.

CHEMICAL NAME
- Phosphoric acid, ortophosphoric acid.

DESCRIPTION
- **Physical characteristics.** Syrup consistency, limpid, colorless, odorless liquid, with very acidic flavor however, pleasant.
- **Solubility.** Miscible in water and ethanol in every proportion.
- **Incompatibilities.** Silver, calcium, iron, magnesium, lead, bismuth salts, ammonium molybdate, organic nature substances, alkalis, alkaline carbonates, glycosides and lactose.

Physical-chemical constants.
- *Relative density* **(5.2.5) FB 5**: 1.87 g/mL at 25 °C.

IDENTIFICATION

A. Dilute 1 mL of the sample into 5 mL of purified water. This solution is acidic to litmus paper.

B. Dilute 0.1 mL of the sample into 5 mL of purified water, neutralize the solution with sufficient quantity of sodium hydroxide solution. Add some drops of the silver nitrate solution at 1% (p/v). The formation of yellow precipitation is observed, soluble in ammonium hydroxide and also in diluted nitric acid.

C. Add to the ammonium molybdate solution at 10% (p/v), drops of phosphoric acid soltution at 10% (p/v). Heat at a temperature which does not exceed 40 °C. The formation of yellow precipitation is observed.

D. Add at 5 mL of the aqueous solution of phosphoric acid at 10% (p/v), the excess of ammonium hydroxide until its saturation. To the obtained solution, add drops of the magnesium mixture. The formation of white precipitation is observed insoluble in ammonium hydroxide and soluble in mineral acids.

PURITY TESTING
- **Aluminum and calcium.** At 1 mL of the phosphoric acid solution at 10% (v/v), add drops of solution of ammonium hydroxide at 10% (v/v) until its alkalinization. There must be no precipitation.
- **Arsenic.** At 1 mL of the phosphoric acid solution at 25% (v/v), add 3 mL of the sodium hypophosphite solution at 10% (p/v). Heat for 15 minutes in boiling bain-marie. The solution must not get darker.
- **Chlorides (5.3.2.1) FB 5.** Dissolve 1 g of the sample into 15 mL of purified water. Proceed as described in Limit testing for chlorides. As a maximum 0.005% (50 ppm).
- **Iron (5.3.2.4) FB 5.** Dilute 0.2 g of the sample into purified water and complete the volume for 10 mL by using the same solvent. Proceed as described in Limit testing for iron. As a maximum 0.005% (50 ppm).

This translation does not replace the portuguese version.

- **Phosphorus and hypophosphoric acid.** The 0.5 mL solution of diluted phosphoric acid with 10 mL of purified water must not get darker when it is heat with some drops of silver nitrate solution at 1% (p/v).
- **Heavy metals (5.3.2.3) FB 5.** Use *Method I*. Proceed as described in *Limit testing for heavy metals*. As a maximum 0.001% (10 ppm).
- **Sulfates (5.3.2.2) FB 5.** Dilute 1.5 g of the sample into purified water and complete the volume for 15 mL by using the same solvent. Proceed as described in Limit testing for sulfates. As a maximum 0.01% (100 ppm).

DOSAGE

- Mix about 1.5 g of the sample, weighed with 1 mg accuracy, with 10 g sodium chloride solution in 30 mL of purified water. Entitle with sodium hydroxide *M* SV, using the thymolftalein SI as an indicator. Each mL of sodium hydroxide *M* SV is equivalent to 0.049 g of H_3PO_4.

PACKAGING AND STORAGE

- In a neutral, amber, tight closed vessel with ground glass cap.

DERIVATIVE FORM

- **Start-up.** Concentrated phosphoric acid (H_3PO_4).
- **Inert input.** Use purified water up to 3 CH or 6 DH and, for others, follow the general rule of preparation of derivative pharmaceutical forms.
- **Method.** *Hahnemann's Method* **(11.1),** *Korsakov's Method* **(11.2),** *Continuous flow method* **(11.3).**
- **Dispensing:** From 2 CH to 3 CH or from 3 DH to 6 DH, prepare in purified water (extemporaneous preparation). From 4 CH or 7 DH, follow the general rule of dispensing.
- **Packaging and Storage.** In a neutral, amber, tight closed vessel.

This translation does not replace the portuguese version.

ACIDUM SALICYLICUM

- $C_7H_6O_3$; 138.12 [*69-72-7*]
- It contains, as a minimum, 99.5% and, as a maximum, 101.0% of $C_7H_6O_3$, calculated in relation to the desiccated substance.

HOMEOPATHIC SYNONYMY
- Salycili acidum.

CHEMICAL NAME
- Salicylic acid, 2-hydroxybenzoic acid.

DESCRIPTION
- **Physical characteristics.** Spongy, white and crystalline powder or white crystals, generally under the shape of fine needles, odorless with initially sweet flavor, which becomes sour thereafter. The synthetic product is white and odorless. The product from natural substances is slightly yellow or rosaceous and with slight methyl salicylate odor.
- **Solubility.** Little soluble in water, very soluble in acetone, easily soluble in ethanol and ethyl ether, slightly soluble in chloroform and fatty oils.

Physical-chemical constants.
- *Melting range* **(5.2.2) FB 5**: 158 °C to 161 °C.

IDENTIFICATION
- *The identification tests* **B.** *and* **C.** *may be obtained if the test* **A** *is performed.*

A. The absorption spectrum in infrared **(5.2.14) FB 5** of the sample, previously desiccated, dispersed in potassium bromide, presents maximum absorption only on the same wave lengths and with the same intensity relating to those observed in the salicylic acid spectrum SQR, prepared in the identical manner.

B. Solubilize 0.1 g of the sample, cold, in sulfuric acid. Add some sodium nitrate crystals. The red color is dissolved.

C. Add to any saturated aqueous solution of the sample one drop of the ferric chloride SR. The purple color is developed that, by adding the ammonium hydroxide, becomes brown-green. The strong mineral acids, some bases and different salts impede this reaction.

PURITY TESTING
- **Easily carbonizable substances.** Dissolve 0.5 g of the sample into 5 mL of sulfuric acid SR. There is no development of clearly brown color before 20 minutes.
- **Phenol.** Dissolve 0.5 g of the sample into 10 mL of the sodium carbonate SR, stir with 10 mL of ethyl ether and let it rest until the ethereal phase is decanted. Desiccate the ethereal phase with anhydrous sodium sulfate and filter it. A 5 mL volume of the filtered product, abandoned to the expontaneous evaportation, leaves, as a maximum 0.001 g of residue. Dissolve the residue into hot water, add ammonium hydroxide and some drops of sodium hypochlorite SR. The blue color is developed.
- **Chlorides (5.3.2.1) FB 5.** Dissolve, under heating, 1.5 g of the sample into 75 mL of distilled water. Let it cool down, add distilled water until the initial volume is completed and filter it. 25 mL volume of the filtered product does not contain more chloride than the product

corresponding to 0.1 mL of the hydrochloric acid 0.02 *M*. As a maximum, 0.014% (140 ppm).

- **Heavy metals (5.3.2.3) FB 5.** Use *Method I*. Dissolve 1 g of the sample into 25 mL of acetone. Add 2 mL of water, 2 mL of acetate buffer pH 3.5 and 1.2 mL of thioacetamide SR. Homogenize and let it rest for 5 minutes. The color produced is not more intense than the color obtained in the *Standard preparation*, prepared with 25 mL of acetone, 2 mL of *Standard lead solution (10 ppm)* and treated in the same way as the sample. As a maximum 0.002% (20 ppm).
- **Sulfates (5.3.2.2) FB 5.** At 25 mL of the filtered product, obtained in *Chlorides*, add two drops of hydrochloric acid and five drops of barium chloride SR. The obtained preparation is not more opalescent than 0.1 mL of sulfuric acid 0.01 *M*. As a maximum, 0.02% (200 ppm).
- **Loss by desiccation (5.2.9) FB 5.** Determine in 1 g of the sample. As a maximum 0.5%.
- **Sulfated ashes (5.2.10) FB 5.** Determine in 1 g of the sample. As a maximum 0.05%.

DOSAGE

- Weigh exactly about 0.5 g of the sample and dissolve into 25 mL of ethanol, previously neutralized with sodium hydroxide 0.01 *M*. Use phenolftalein SI as indicator and entitle with sodium hydroxide 0.1 *M* SV, until the rosaceous color appears. Each mL of sodium hydroxide 0.1 *M* SV is equivalent to 13.812 mg of $C_7H_6O_3$.

PACKAGING AND STORAGE

- In a neutral, amber, hermetically closed glass vessel, protected from light.

DERIVATIVE FORM

- **Start-up.** Salicylic acid ($C_7H_6O_3$).
- **Inert input.** Ethanol at 90% (v/v).
- **Method.** *Hahnemann's Method* **(11.1),** *Korsakov's Method* **(11.2),** *Continuous flow method* **(11.3).**
- **Dispensing:** From 1 CH and 1 DH, ethanol will be used in the same ethanolic title as their initial dissolvents, in the first three dynamizations, for the centesimal scale and in the first six dynamizations for the decimal scale. Hence, use dispensing ethanol.
- **Packaging and Storage.** In a neutral, amber, tight closed vessel.

This translation does not replace the portuguese version.

ACIDUM SULPHURICUM

- H_2SO_4; 98.08 [*7664-93-9*]
- It contains, as a minimum, 95% and, as a maximum, 97% of H_2SO_4.

HOMEOPATHIC SYNONYMY
- Sulphuris acidi.

CHEMICAL NAME
- Sulfuric acid.

DESCRIPTION
- **Physical characteristics.** Colorless, oily, odorless, hygroscopic liquid. Extremely corrosive. It is acidic to the indicative litmus paper.
- **Solubility.** Miscible with water and ethanol in all of the proportions developing a considerable warmth, and it must be carefully and slowly added, under constant stirring and, preferably, under running water bath.
- **Incompatibilities.** Carbonates, alkaline and metallic cyanides, oxides in general.

Physical-chemical constants.
- *Relative density* **(5.2.5) FB 5**: 1.84.
- *Boiling temperature* **(5.2.3) FB 5**: 290 C.

IDENTIFICATION

A. In a porcelain capsule, place 0.1 g of sucrose. Add, then, two drops of the sample. The sucrose carbonization is observed, which is accelerated by the heating.

B. Prepare the *Solution (1)* and test for sulfate anion described as follows.
- *Solution (1)*: neutralize 5 mL of the sample at 5% (v/v), with sufficient quantity of the sodium hydroxide solution at 5% (p/v).
  a) At 2 mL of the *Solution (1)*, add five drops of aqueous barium chloride solution at 1% (p/v). The formation of white precipitation is observed.
  b) At 2 mL of the *Solution (1)*, add five drops of aqueous lead acetate solution at 1% (p/v). The formation of white precipitation is observed, which is solubilized by adding sufficient quantity of aqueous ammonium acetate solution at 1% (p/v).
  c) At 2 mL of the *Solution (1)*, slowly add five drops of aqueous strontium chloride solution at 1% (p/v). The formation of yellow precipitation is observed, which may be accelerated by heating.

PURITY TESTING
- **Reducing substances (sulfurous acid, nitrous acid).** At 5 mL of the aqueous acid solution at 20% (v/v), add five drops of aqueous potassium permanganate solution at 1% (p/v). The resulting color must be stable for 5 minutes, as a minimum.
- **Arsenic and Selenium** Add 1 mL of the sample at 2 mL of purified water and let it cool down. Add 3 mL of aqueous sodium hypophosphite solution at 1% (p/v). Heat for 15 minutes in boiling bain-marie. There must not be any darkening in the solution.
- **Chlorides.** To the aqueous solution of the sample at 5% (v/v), add five drops of aqueous solution of silver nitrate at 1% (p/v). There is no precipitatio or turbidity.

This translation does not replace the portuguese version.

- **Heavy metals.** To the aqueous solution of the sample at 10% (v/v), previously neutralized with ammonium hydroxided, and acidified thereafter with sufficient quantity of aqueous acetic acid solution at 10% (v/v), add five drops of aqueous sodium sulfide solution at 1% (p/v). There is no precipitatio or turbidity.

DOSAGE
- Weigh 2 g of the sample, add to 40 mL of purified water. Entitle with sodium hydroxide *M* SV, using the methyl orange SI as an indicator. Each mL of sodium hydroxide *M* SV is equivalent to 0.04904 g of H_2SO_4.

PACKAGING AND STORAGE
- In a neutral, amber, hermetically closed vessel.

DERIVATIVE FORM
- **Start-up.** Sulfuric acid (H_2SO_4).
- **Inert input.** Purified water up to 3 CH or 7 DH, hydroalcoholic solution in different gradations from 4 CH or 8 DH.
- **Method.** *Hahnemann's Method* **(11.1),** *Korsakov's Method* **(11.2),** *Continuous flow method* **(11.3).**
- **Dispensing:** Dispense only from 3 CH or 6 DH in purified water. From 4 CH or 8 DH, dispense in dispensing alcohol.
- **Packaging and Storage.** In a neutral, amber, tight closed vessel.

This translation does not replace the portuguese version.

ADRENALINUM

- $C_9H_{13}NO_3$; 183,21 [*51-43-4*]
- Contains, at least, 97% and at most, 100.5%, calculating according to the dry base.

HOMEOPATHIC SYNONYM
- Epinephrinum.

CHEMICAL NAME
- Epinephrine

DESCRIPTION
- **Physical features.** Microcrystalline powder, almost white or slightly yellowish, alterable to air and light, with gradual darkening, odorless, light bitter flavor.
- **Solubility.** Practically insoluble in water, in ethyl ether, ethanol and chloroform. Soluble in mineral acids and alkaline hydroxides.
- **Incompatibilities.** Alkali, copper, iron, silver, zinc, other metals, gums, oxidizing agents, tannin.
- **Physical-chemical constants**
- *Melting point* **(5.2.2) FB 5**: 212 C.

IDENTIFICATION

A. The infrared absorption spectrum **(5.2.14) FB 5** of the sample, disperse in potassium bromide, presents peaks of absorption in the same wavelengths and with the same relative intensities of those observed in the epinephrine spectrum SQR.

B. The infrared absorption spectrum **(5.2.14) FB 5**, from a solution of the sample 30 mg/mL in hydrochloric acid 0,01 *M*, shows maximum in 280 nm, identical to the observed in the spectrum of similar solution of epinephrine SQR.

C. With 1mL of a acid solution of epinephrine 0.1% (p/v) add 1mL of 2,5-dietoxitetrahydrofuran solution 1% (v/v) in glacial acetic acid. Heat to 80 °C for 2 minutes, cool in ice bath and add 3mL of *p*-dimetilaminobenzaldehyde solution 2%(p/v) in hydrochloric acid and glacial acetic acid. (1:19). Mix and let it rest for 2 minutes. The solution presents yellow coloring similar to a solution prepared identically, but concealing the substance in analysis (differentiation of noradrenaline).

D. With 5 mL of acid ftalo buffer pH 4.0 add 0.5 mL of acid solution of epinephrine and 1 mL of iodine 0.1 *M*. Mix and let it rest for 5 minutes. Add 2 mL of solution of sodium thiosulphate 2,5% (p/v). It develops a red coloring.

E. Dissolve 0.01 g of the sample in 10 mL of acetic acid 0,2% (v/v). With 2 mL of this solution add a drop of ferric chloride SR. It develops a intense green coloring that becomes red by the addition of sodium bicarbonate 1% (p/v).

PURITY TESTS
- **Adrenaline.** The absorptivity of a solution containing 2 mg/mL in hydrochloric acid (1:200), 310 nm, it's not higher than 0.2.
- **Norepinephrine.** Proceed as described in *Thin-layer chromatography* **(5.2.17.1) FB 5**, using silica gel G, as support, and mix of 1-butanol, water and formic acid (7:2:1), as mobile phase. Apply, separately, to the plate, 5 µL of each of the solutions, recently prepared, described hereinafter.

This translation does not replace the portuguese version.

- *Sample solution:* dissolve 220 mg of the sample in 2mL of formic acid. Dilute with methanol 10 mL, obtaining final concentration of 20 mg/mL.
- *Standard epinephrine solution*: dissolve 200 mg of epinephrine SQR in 2 mL of formic acid and dilute with methanol 10 mL, obtaining final concentration of 20 mg/mL.
- *Standard norepinephrine solution*: dissolve 40 mg of norepinephrine SQR in 1 mL of formic acid and dilute with methanol 25 mL, obtaining final concentration of 1.6 mg/mL.
- Develop a chromatogram in a route of 10 cm. Remove the plate, let ir air-dry. Examine under ultraviolet light (254 nm). The rating of the Rf of the main stain obtained on the chromatogram of the
- *Sample solution* matches the Rf obtained for the *Standard norepinephrine solution*. No stain obtained on chromatogram of the *Sample solution* must be bigger or intenser than the stain with the same Rf rating obtained on chromatogram of the *Standard norepinephrine solution*, matching no more than 4% of norepinephrine.
- **Loss by desiccation (5.2.9) FB 5.** Desiccate, reduced pressure, over silica gel for 18 hours in room temperature. It must not loose more than 2% of its weight.
- **Sulphated ash (5.2.10) FB 5.** At most 0.1%, using 1g from the sample.

ASSAY

- Proceed as described in *Titration in a non-aqueous medium* **(5.3.3.5) FB 5**. Weigh 0.3 g of the sample and dissolve in 50 mL of glacial acetic acid SR slightly heating if necessary. Titrate with perchloric acid 0,1 *M* SV, using methylrosaniline chloride SI as a indicator. Perform a blank test and make the necessary corrections. Each mL of perchloric acid 0,1 *M* SV correspond to 18,32 mg of $C_9H_{13}NO_3$.

PACKAGING AND STORAGE

- In hermetic, opaque and refrigerated containers. Ideally in containers in which the air has been replaced with nitrogen.

DERIVED FORM

- **Starting point.** Epinephrine ($C_9H_{13}NO_3$).
- **Inert ingredient.** Lactose.
- **Method.** *Hahnemannian Method* **(11.1)**, Korsakovian Method **(11.2)**, *Streaming Method* **(11.3)**.
- **Dispensation.** From 4 DH-trit. or 2 CH-trit.
- **Packaging and storage.** In a neutral, amber and tightly closed container.

This translation does not replace the portuguese version.

AESCULUS HIPPOCASTANUM

- *Aesculus hippocastanum* (L.) – HIPPOCASTANACEAE

HOMEOPATHIC SYNONYM
- Castanha equina, Hippocastanum vulgare.

EMPLOYED PART
- Dry shelled seed.

PLANT DESCRIPTION
- *Aesculus hippocastanum* L. is a tree of 12 m to 18 m high, with branches, with smooth and white woody cortex, with a not to hough wood. The leaves are opposite, bright green, straight, with printing and oval. The leaflets are sharp and closed. The flowers show up with numerous rosy and white pyramidal racemes. The fruit is big, straight, brown, with a big and pale round scar, surrounded by fleshy peel covered by thorns.

MACROSCOPIC DESCRIPTION
- The seeds are hard and exalbuminated, 2.5 cm to 4.0 cm, irregularly sub spherical, flattened on both poles or only on hilo, or yet flattened in a irregular way by desiccation. The fractured seed shows testa of brown color, brittle, 1.0 mm to 2.0 mm of thickness, enveloping the embryo, which possess a little radicle and two big horny and starchy cotyledons, of external light-brown color and almost white in the fracture. Endosperm missing. The testa is straight, leathery, brittle, easily separable from embryo in some parts, reddish-brown or light-brown coloring, usually glossy, rarely opaque and with a big white stain, correspondent to the hilo. The radicle is curve and inhabit a slump over the cotyledons comissure or over the dorsal side of one of the two cotyledons and is clearly prominent on external surface.

MICROSCOPIC DESCRIPTION
- Front view, seed's testa shows a epidermis of yellowish-brown coloring, with uniform cells, the most part of them being polygonal or rounded. Transversal section, the epidermis cells are columnar and compact, with thick and flat cuticle and external periclinal walls much thicker than inner walls. Up to four distinct zones can be seen below. The first, the outermost, is composed by some layers of colenchyme cells of brownish-yellow coloring. The second one is composed by ten or more layers of esclerenchyme cells, tangentially flats. The third is composed by four to ten layers of parenchyme cells, colorless, in a polyhedral form and with more thin walls than the previous regions, presenting intercellular spaces. On the more external layers of this region, the vascular bundles can be seen. The fourth regions, if existent, is composed by some layers of cells tangentially flats and thick walls. The cotyledons are composed by amilífero parenchyma, covered by a unistratified epidermis. Frontal view, the epidermis cells of the cotyledons are polygonal. The reserve parenchyma have oval-shaped to elliptical cells, with thin walls, smaller on the outermost region and gradually bigger towards the interior, containing grains of starch and lipidic drops. Delicate vascular bundles take place in this parenchyma; the vessel elements are narrow and have thickening of helical wall. The starch grains are simple, may be spherical, oval-shaped and piriform, and of different sizes, ranging from 2 μm to 80 μm of diameter. The smaller grains have hilo usually in the form of a dot; the others, more numerous, present hilo, in the form of a cross, with branches or starry.

This translation does not replace the portuguese version.

MICROSCOPIC DESCRIPTION OF POWDER

- The powder meets all established requirements for the species, with the exception of the macroscopic characters. Are distinctive: irregular fragments of testa, golden-yellow, with irregular contour cells, strongly interlinked, whose limits are unrecognizable, with extensions of the cellular wall appearing tubiforms, with narrow lume, similar to the fibers in transversal section; fragments testa showing thickened walls; fragments of the testa epidermis, on front view, with periclinal walls evenly thickened, and, when in transversal section, with radial walls and external periclinal strongly thickened, resembling a thick palisade, with reddish-brown cells; fragments of the reserve parenchyma, with flattened and elliptical cells, containing starch grains and lipidic drops; fragments of reserve parenchyma with portions of vascular bundles; plenty starch grains, isolated or in groups, of different sizes and shapes, as described. When submitted to cold chloral hydrate, the starch immediately swells. On the fragments of cotyledon tissues, submitted to long cooking, the starch doesn't looses the characteristically sticky character. On this tissues, colorless lipid drops can be seen on cells interior as well as spread around the fragments.

PREPARATION OF MOTHER TINCTURE

- Proceed as described in *Preparations of mother tincture with plant origin* **(10.1)**. The mother tincture of *Aesculus hippocastanum* is prepared via maceration or percolation, in a way that the alcoholic strength, during and by the end of the extraction, is of 65% (v/v) according to the general technique of preparation of mother tincture.

MOTHER TINCTURE CHARACTERISTICS

- Liquid of yellow coloring and almost odorless.

IDENTIFICATION

A. With 1 mL of mother tincture, add 1 mL of purified water. Turbidity or precipitate are not produced.

B. With 1 mL of mother tincture, add 1 mL of purified water. Abundant foaming, by agitation, is developed.

C. With 1 mL of mother tincture, add 1 mL of hydrochloric acid and a fragment of metallic magnesium. A rosy coloring is developed of variable intensity.

D. With 2 mL of mother tincture, add some drops of ferric chloride solution at 10% (p/v). A dark green coloring is developed.

E. Proceed as described in *Thin-layer chromatography* **(5.2.17.1) FB 5**, using silica gel G, as support, and mix of chloroform, glacial acetic acid, methanol and water (15:8:3:2) as mobile phase. Apply, to plate 20 μL of mother tincture. Develop a chromatogram in a route of 10 cm. Remove the plate, let it air-dry. Examine under ultraviolet light (365 nm). Two drab stains can be seen between the Rfs 0,15 and 0,35. Nebulize the chromatoplate with a aluminum chloride solution and examine under ultraviolet light (365nm). The stains between the Rfs 0,15 and 0,35 appear with a yellow flowering. Develop a second chromatogram, with the same previous conditions and nebulize a sulphuric acid solution at 1% (p/v) in ethanol at 90% (v/v). Examine under natural light. The chromatogram presents three yellow stains between the Rfs 0,15 and 0,35. Heat the plate to a temperature of 100 °C and 105 °C for 10 minutes and examine under natural light. The chromatogram presents three purple stains, slightly separated, between the Rfs 0,40 and 0,55. Three or four grayish-drab stains could appear with Rf inferior to 0.40.

PURITY TESTS

- **Title in ethanol.** Must be between 60% and 70% (v/v).
- **Dry residue.** Must be 1,1% (p/v) or higher.

PACKAGING AND STORAGE

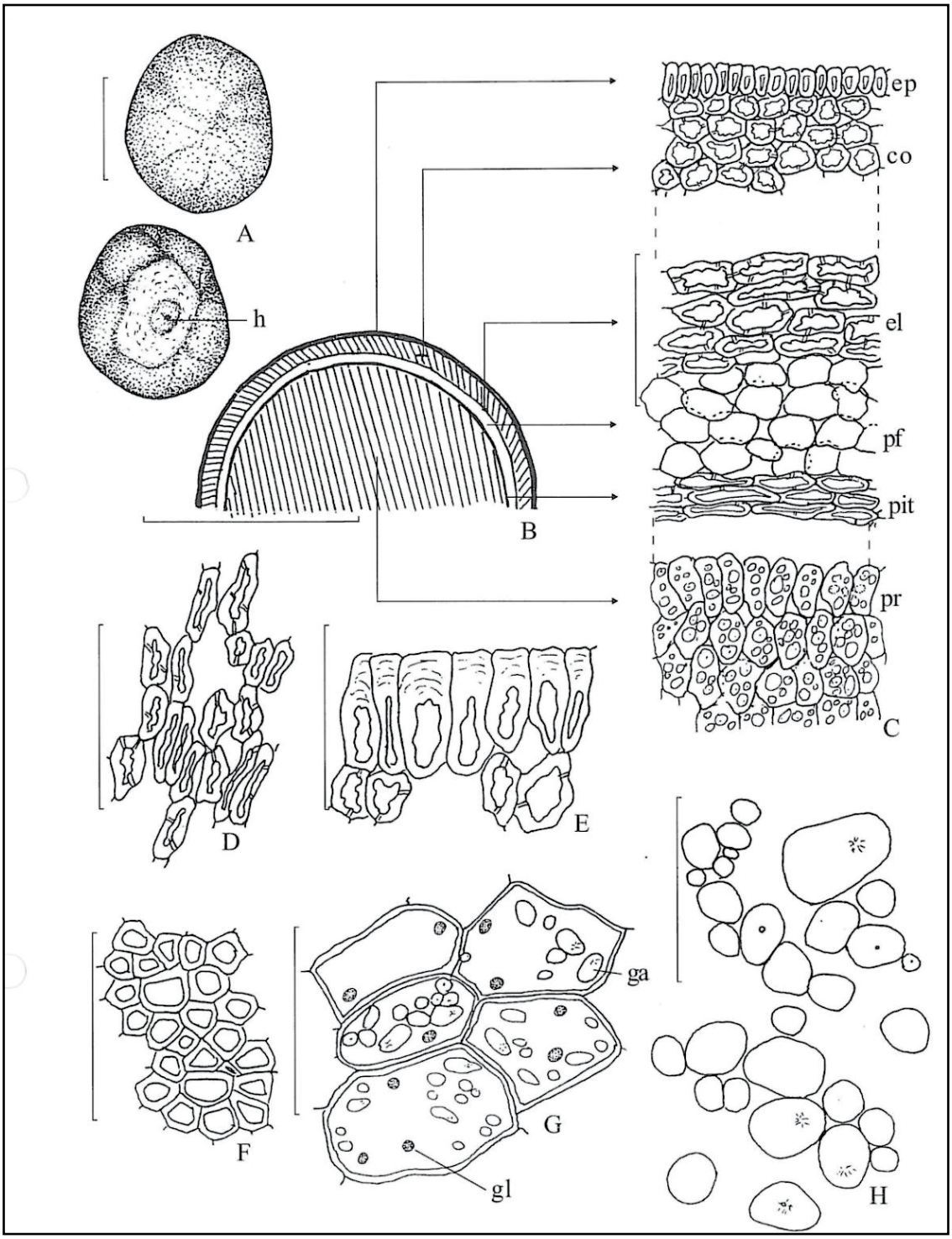
- In a neutral glass, amber, tightly close container, safe from light and heat.

DERIVED FORM

- **Starting point.** Mother tincture.
- **Inert ingredient.** From 1 CH to 3 CH or 1 DH to 6 DH, use the same alcoholic strength of mother tincture. For other dynamizations, follow the general rule of preparation of derived pharmaceutical forms.
- **Method.** *Hahnemannian Method* **(11.1)**, Korsakovian Method **(11.2)**, *Streaming Method* **(11.3)**.
- **Dispensation.** From mother tincture, following the general rule of dispensation.
- **Packaging and storage.** In a neutral glass, amber, tightly close container, safe from light and heat.

This translation does not replace the portuguese version.

Picture 1 – Macro and microscopic aspects in *Aesculus hippocastanum* L.



Subtitle complement of **Picture 1.** The scales correspond in **A** and **B** ate 0.5 cm; in **C** at 300 μm;; in **D** and **G** at 100 μm; in **H** at 50 μm. **A**- schematic representations of seed, in abaxial view and in adaxial view, showing the hilo region; **B** - schematic representations of seed, in transversal section; **C** - schematic representations of seed, in transversal section, as showed in **B**; **D** - detail of the epidermis of seeds integument in frontal view; **E** - detail of testa epidermis, in transversal section; **F** - esclerenchimal cells, in transversal section; **G** - cells of cotyledonary reserve parenchyma; **H** - starch grains; collenchyma (co); esclerenchyma (el); epidermis (ep); starch garins (ga); lipidic drop (gl); hilo (h); fundamental parenchyma (pf); internal parenchyma of testa (pit), with thick cellular walls; reserve parenchyma of cotyledon (pr).

This translation does not replace the portuguese version.

PURIFIED WATER

- H_2O; 18,02 [*7732-18-5*]
- Purified water is drinking water that has been through some type of treatment to remove possible contaminants and meet the requirements of purity established in this dissertation. Is prepared by distillation, ion exchange, reverse osmosis or by any other adequate process. Must be free of addition of any dissolved substances. Generally used in the preparation of medicines that don't require sterile or apyrogenic water, destined for non-parenteral use.

DESCRIPTION
- **Physical features.** Clear, colorless, tasteless and odorless liquid.

PURITY TESTS
- **Acidity or alkalinity.** Add 0.05 mL of methyl red SI in 10 mL of recently boiled and cooled sample in a borosilicate flask. The solution doesn't develop red coloring. Add 0.1 mL of bromitol blue SI in 10 mL of the sample. The solution doesn't develop blue coloring.
- **Oxidizable substances.** Boil 100 mL of sample with 10 mL sulphuric acid M. Add 0.2 mL of potassium permanganate 0,02 *M* SV and let it boil for 5 minutes. The remaining solution is slightly rosy.
- **Water (5.2.24) FB 5 conductivity.** At most 1,3 µS/cm at (25 ± 0,5) °C. The user must define the proper maximum limit for the specific application **(11) FB 5**. Alternatively replace the tests for ammonium, calcium, chlorides, nitrates and sulfates.
- **Total organic carbon (5.2.30) FB 5.** Alternatively, replace the test for oxidizable substances. At most 0,5 mg/L.
- **Ammonium.** Add 1 mL of iodide of alkaline mercury potassium SR1 in 20 mL of the sample. After 5 minutes, examine the solution in the vertical axis of the tube. The solution is no more intensely colored than the standard by the adding of 1 mL of iodide of alkaline mercury potassium SR1 in a
- mix of 4 mL of standard ammonium solution (1 ppm NH4) and 16 mL of water with no ammonium. At most 0,00002% (0,2 ppm).
- **Calcium and magnesium.** Add 2 mL of ammonium chloride buffer pH 10,0, 0,5 mL of eriochrome black T SI and 5 mL of disodium edetate 0,05 *M* in 100 mL of the sample. A blue clear coloring is produced. At most 0,0001 (1 ppm).
- **Chlorides.** Add 1 mL of nitric acid SR and 0,2 mL of silver nitrate 0,1 *M* in 10 mL of the sample. The solution doesn't present alterations in the appearance for, at least, 15 minutes.
- **Nitrates.** Transfer 5 mL of the sample to the test tube immersed in cold water, add 0,4 mL of potassium chloride solution at 10% (p/v) and 0,1 mL of diphenylamine solution at 0,1% (p/v). Drip, with agitation, 5 mL of sulphuric acid free of nitrogen. Transfer tube to water-bath at 50 °C. After 15 minutes, any blue coloring developed in the solution is no more intense than the standard's, simultaneously prepared and in the same way, using a mix of 4,5 mL of water without nitrate and 1 mL of the nitrate
- standard solution (2 ppm NO3), recently prepared. At most 0,00002% (0,2 ppm).
- **Sulphates.** Add 0,1 mL of hydrochloric acid 2 *M* and 1 mL of aqueous solution of barium chloride at 6,1% (p/v) in 10 mL of the sample. The solution doesn't present alterations in the appearance for at least 1 hour.

This translation does not replace the portuguese version.

TESTS OF BIOLOGICAL SAFETY

- **Counting of the total number of mesophile microorganisms (5.5.3.1.2) FB 5.** Fulfill the test. Proceed as described for water-soluble substances in method of filtration by membrane or other methodology that is equal or superior to the validated pharmacological method. Use at least 200 mL of the sample. At most 100 UFC/mL
- Another test that can be performed in replacement of the previously described is the one of the counting of heterotrophic bacteria. At most 100 UFC/mL When the purified water is collected from the packaging reservoir, besides the counting of the total number of mesophilic microorganisms or heterotrophic bacteria, must be performed the *Research of pathogenic microorganisms* **(5.5.3.1.3) FB 5**: absence of total coliforms, *Escherichia coli* and *Pseudomonas aeruginosa*, specially if the water is to be used in topical use products. Use 1oo mL of water in the test.
- The practice of sterile purified water, used in the preparation of eye drops and other processes that can't go through final sterilization by heat or filtration, must attend additionally to the *Sterility Test* **(5.5.3.2.1) FB 5**.

PACKAGING AND STORAGE

- In inert containers, such as glass or stainless steel 316L polished, properly identified, that ensure the required physical-chemical and microbiological properties. In case stock up is necessary, the purified water must be stored and distributed in proper conditions to prevent the microbial growth and avoid any other contamination.

This translation does not replace the portuguese version.

ALCOHOL

- C_2H_6O; 46,07 [*64-17-5*]
- Contain, at least, 95,1% (v/v), corresponding to 92,55% (p/p), and, at most, 96,9% (v/v),
- corresponding to 95,16% (p/p) of C2H6O at 20 °C, calculated from the relative density applying the *Alcoholic strength chart (20 °C)* **Annex C**. For absolute ethyl acid, contains, at least, 99,5% (v/v),
- corresponding to 99,18% (p/p) of C2H6O at 20 °C, calculated from relative density applying the
- *Alcoholic strength chart (20 °C)* **Annex C**.

DESCRIPTION
- **Physical features.** Colorless, clear, volatile, flammable and hygroscopic liquid.
- **Solubility.** Miscible with water and methylene chloride.

Physical-chemical constants.
- *Relative density* **(5.2.5) FB 5:** 0,805 to 0,812, determined at 20 °C. For absolute ethyl alcohol, no more than 0,793, determined at 20 °C.

IDENTIFICATION
- The absorption spectrum in infrared only **(5.2.14) FB 5** of the sample presents peaks of wave on the same observed lengths on the absorption and with the same relative intensities of those ethanol spectrum SQR.

PURITY TESTS
Clarity of the solution (5.2.25) FB 5. Prepare the solutions and suspensions described below.
- *Hydrazine solution:* transfer 1 g of hydrazine sulphate to a volumetric flask of 100 mL, dissolve and complete the volume with water and stir. Let it rest for 4 hours to 6 hours.
- *Methenamine solution:* transfer 2,5 mg of methenamine to a volumetric flask of 100 mL, add 25 mL of water and stir till it dissolves.
- *Primary opalescent suspension*: transfer 25 mL of the *Hydrazine solution* to the volumetric flask of 100 mL containing the *Methenamine solution*. Stir and let it rest for 24 hours.

***Note:** the primary opalescent suspension is stable for 2 months, if kept in a closed glass flask with no defects. The suspension could adhere to the glass and must be stirred before use.*
- *Opalescent standard*: transfer 15 mL of the *Primary opalescent suspension* to a volumetric flask of 100 mL, complete the volume with water and stir.

***Note:** the Opalescent standard must not be used after 24 hours of prepare.*
- *Reference standards*: transfer 5 mL of the *Opalescent standard* to a volumetric flask of 100 mL, complete the volume with water and stir to obtain a *Suspension of reference A*. Transfer 10 mL to other flask of 100 mL, complete with water and stir to obtain the *Suspension of reference B*.
- *Sample solution A*: sample to be examined.
- *Sample solution B*: dilute 1 mL of *Sample solution A* for 20 mL of water and let it rest for 5 minutes before use.

This translation does not replace the portuguese version.

- *Procedure*: transfer a portion of *Sample solution A* and of *Sample solution B* to tubes of colorless and transparent glass with inner diameter between 15 mm and 25 mm, in such a way to obtain approximately 40 MM of depth. Transfer to similar tubes the same volume of *Suspension of reference A*, *Suspension of reference B* and to another tube the same quantity of water. Compare the *Sample solution A*, *Sample solution B*, *Suspension of reference A*, *Suspension of reference B* and water, applying dark background and light. The *Sample solution A* and *Sample solution B* have the same water clarity or don't present bigger opalescence than *Suspension of reference A*.

Liquids color (5.2.12) FB 5. Prepare the solutions described below.

- *Stock standard solution*: combine 3 mL of *Base solution of ferric chloride*, 3 mL of *Base solution of cobalt chloride II*, 2,4 mL of *Base solution of cupric sulphate* and 1,6 mL of diluted hydrochloric acid (10 mg/mL).
- *Standard solution*: transfer 1 mL of *Stock standard solution* to a volumetric flask of 100 mL, complete the volume with diluted hydrochloric acid (10 mg/mL) and stir. Use this solution right after the prepare.
- *Procedure*: transfer a portion of *Standard solution* to a colorless and transparent glass tube with inner diameter between 15 mm and 25 mm, in such a way to obtain approximately 40 MM of depth. Transfer to a similar tube the same volume of sample and to another tube the same quantity of water. *Sample solution A* doesn't have a more intense coloring than the *Standard solution*.
- **Acidity or alkalinity.** Add 20 mL of water without carbon dioxide to 20 mL of the sample and add 0,1 mL of phenolphthalein SI. The solution must be colorless. Add i mL of sodium hydroxide 0,01 *M*. The solution becomes pink (30 ppm, expressed as acetic acid).
- **Light absorption.** Record the absorption spectrum on sample's ultraviolet between 200 nm and 400 nm applying bucket of 1 cm of light path, using water as blank. Maximum absorbency of 0,08 in 240 nm, 0,06 between 250 nm and 260 nm and 0,02 between 270 nm and 340 nm.
- **Limit of non-volatile residues.** Evaporate 100 mL of sample in water bath and dry the residue at 105 °C for 1 hour. Cool it in desiccator and weight. The residue weights no more than 2,5 mg. At most 0,025%
- **Organic impurities.** With 5 mL of the sample, add purified water, gradually, by flask walls, till it completes 50 mL. The mix must not cloud, even if fleetingly.

ASSAY

- Determine the quantity of C2H6O at 20 °C, from the relative density applying the *Alcoholic strength chart (20 °C)* **Annex C**.

PACKAGING AND STORAGE

- In tightly closed containers.

This translation does not replace the portuguese version.

ALLIUM CEPA

- *Allium cepa* (L.) – LILIACEAE

HOMEOPATHIC SYNONYM
- Cepa.

EMPLOYED PART
- Fresh bulb.

PLANT DESCRIPTION
- *Allium cepa* L. is a bulbous plant with erect, concave and dilated trunks on the base, with green, long and fistulous leaves. The flowers are whitish, greenish and pink, grouped in rounded umbels arranged on the trunk extremity, presenting two to four short bracts. The fruit is a small capsule.

DRUG DESCRIPTION
- The bulb, usually round and flat, of variable diameter. Is covered by thin scales of pale, whitish, yellow or reddish coloring, according to the variety, involving successive, internal, whitish, thick, juicy layers with characteristic odor.

PREPARATION OF MOTHER TINCTURE
- Proceed as described in *Preparations of mother tincture from fresh plants* **(10.1.2).** The mother tincture of *Allium cepa* is prepared via maceration or percolation, in a way that the alcoholic strength, during and by the end of the extraction, is of 65% (v/v) from the fresh bulb of *Allium cepa* L according to the general technique of preparation of mother tincture.

MOTHER TINCTURE CHARACTERISTICS
- Liquid of yellowish coloring, roughly intense or slightly reddish, of characteristic odor and flavor.

IDENTIFICATION

A. Add to 2 mL of mother tincture, tow drops of Tollens reagent. A cold dark precipitated is formed. After heating in boiling water bath, for 1 to 2 minutes, the formation of silver mirror can be observed.

B. Add to 2 mL of mother tincture, in a test tube, 0,1 g of zinc stearate powder, and 1 mL of concentrated hydrochloric acid. On the superior extremity of the tube, place a strip of paper of lead acetate. Heat in boiling water bath, till boiling. The lead acetate paper acquires a gray to black coloring.

C. Add to 2 mL of mother tincture, five drops of ferric chloride solution at 10% (p/v). It develops a yellow coloring.

D. Add to 2 mL of mother tincture, five drops of alkaline cupric tartrate SR. A immediate reduction, by cold, is observed with the developing of a yellowish-green coloring. Next, heat in water bath, for 1 to 2 minutes, it's observed the color change to ocher yellow, with formation of precipitated.

E. Add to 2 mL of mother tincture, five drops of ninhydrin solution at 1% (p/v) in ethanol at 96% (v/v). Heat in boiling water bath for 1 to 2 minutes. It develops a purple coloring.

This translation does not replace the portuguese version.

F. Add to 2 mL of mother tincture, five drops of aluminum chloride solution at 1% (p/v). It develops a golden-yellow coloring.

G. Add to 2 mL of mother tincture, five drops of lead acetate solution at 1% (p/v). It develops a orange coloring with intense clouding.

H. Add to 2 mL of mother tincture, five drops of copper sulphate solution at 5% (p/v). It develops a yellowish-green coloring.

I. Add to 1 mL of mother tincture, five drops of ferric chloride solution at 10% (p/v). A dark green coloring is developed.

J. Proceed as described in *Thin-layer chromatography* **(5.2.17.1) FB 5**, using silica gel G, as support, and mix of 1-butanol, glacial acetic acid and water (40:10:10) as mobile phase. Apply, to plate 40 μL of mother tincture. Develop a chromatogram in a route of 10 cm. Remove the plate, let it air-dry. Examine under ultraviolet light (365 nm). The chromatogram presents, usually, a stain with yellow fluorescence with Rf close to 0,40 and two others, ocher yellow with Rfs close to 0,70 and 0,85. Next, nebulize the plate with aluminum chloride solution at 1% (p/v). Examine under ultraviolet light (365 nm). The stains with Rf, respectively, 0,70 and 0,85 appear with greenish-yellow fluorescence. Develop a second chromatogram with the same previous conditions and, after drying it, nebulize with Tollens reagent. Examine under visible light. The chromatogram presents a yellow stain with Rf between 0,60 and 0,70, and other, dark brown, with Rf close to 0,95. Stains could appear, violet-gray, with Rf close to 0,20 and brown, with Rf close to 0,35.

PURITY TESTS

- **Title in ethanol.** Must be between 60% to 70% (v/v).
- **Dry residue.** Must be 2% (p/v) or higher.

PACKAGING AND STORAGE

- In a neutral glass, amber, hermetically closed container, safe from light and heat.

DERIVED FORM

- **Starting point.** Mother tincture.
- **Inert ingredient.** From 1 CH to 3 CH or 1 DH to 6 DH, use the same alcoholic strength of mother tincture. For other dynamizations, follow the general rule of preparation of derived pharmaceutical forms.
- **Method.** *Hahnemannian Method* **(11.1)**, Korsakovian Method **(11.2)**, *Streaming Method* **(11.3)**.
- **Dispensation.** From 1 Ch and 1 DH it will be employed ethanol with the same ethanolic title of mother tincture, on the first three dinamizations for the centesimal scale and on the first ones for the decimal scale. Next, employ the hydroalcoholic solution 30% (p/p).
- **Packaging and storage.** In a neutral glass, amber, tightly close container, safe from light and heat.

This translation does not replace the portuguese version.

ALUMEN

- $AlK(SO_4)_2.12\ H_2O$; 474,39 [*7784-24-9*]
- Contains, at least, 99% and at most, 100.5% of $AlK(SO_4)_2$, calculated according to the dry substance.

HOMEOPATHIC SYNONYM
- Alumen crudum, Alumen kalicosulphuricum.

CHEMICAL NAME
- Aluminum sulphate and dodecahydrate potassium.

DESCRIPTION
- **Physical features.** Clear, large and rigid crystals, or its fragments, or crystalline white powder, of sweet and astringent flavor. Odorless.
- **Solubility.** Soluble in water and insoluble in ethanol.
- **Incompatibilities.** Borax, alkaline hydroxide, carbonates, phosphates, calcium salts, lead, mercury and tannin.
- **Physical-chemical constant.**
- *Melting point* **(5.2.2) FB 5**: 92,5 °C.

IDENTIFICATION

A. With 1 g of the sample, add sodium hydroxide *M* (1:20): a precipitate that dissolves with reagent excess is formed. Ammonium detachment must not occur.

B. Add 10 mL of sodium bitartrate in 5 mL of saturate alumen solution: a white crystalline precipitate is formed in 30 minutes.

C. A solution of the sample at 50 mg/mL, responds to the reactions of the potassium ion **(5.3.1.1) FB 5**.

D. A solution of the sample at 5% (p/v) responds to the reactions of aluminum ion **(5.3.1.1) FB 5** and of sulphate **(5.3.1.1) FB 5**.

PURITY TESTS
- **Solution aspect.** Dissolve 2,5 g of the sample in 50 mL of purified water. The solution must be clear **(5.2.25) FB 5** and colorless **(5.2.12) FB 5**.
- **pH.** Must be of 3,0 to 3,5, in sample solution containing 100 mg/mL **(5.2.19) FB 5**.
- **Iron.** Add five drops of potassium ironcyanide SR in 20 mL of a alumen solution (1:150). There is no immediate production of blue coloring.
- **Ammonia (5.3.2.6) FB 5.** Weigh 125 mg of the sample, dissolve with purified water completing 20 mL of the solution. Remove from this solution 1 mL, dilute with purified water till 14 mL. Proceed to *Limit for ammonia rehearsal*. At most 0,2% (2000 ppm).
- **Arsenic (5.3.2.5) FB 5.** At most 0,0003% (3 ppm).
- **Heavy metals (5.3.2.3) FB 5.** Use the *Method 1*. Dissolve 1 g of the sample with 20 mL of purified water and add 5 mL of hydrochloric acid 0,1 *M*. Evaporate till it dries in a porcelain flask. Treat the residue with 20 mL of purified water and add 50 mg of hydroxylamine hydrochloride. Heat the solution in water bath for 10 minutes, cool down and dilute with purified water till 12 mL. Proceed as described in *Limit for heavy metals rehearsal*. At most 0,002% (20 ppm).

This translation does not replace the portuguese version.

- **Sulphated ash (5.2.10) FB 5.** Weigh 1 g of sample and dry in stove at a temperature of 180 °C for 4 hours or till constant weight. At most 43% to 46%.

ASSAY

- Weigh 0,5 g of the sample, dissolve purified water, containing 1 mL of concentrated hydrochloric acid, dilute with purified water till 200 mL. Add 5 mL or 6 mL of hydroxuquinoline solution at 10% (p/v) in acetic acid at 20% (v/v) and 5 g of urea. Cover the beak with watch glass and heat to 95 C for 2 hours to 3 hours. The precipitation is considered complete when the supernatant liquid that was originally yellowish-green becomes orange-yellow. Let it cool down and filtrate through a porosity funnel G-4. Wash, primarily, with hot purified water and at last with cold purified water. Dry it in a stove at 130 C till constant weight. Each gram of the residue is equivalent to 1,0311 g of $AlK(SO_4)_2.12\ H_2O$.

PACKAGING AND STORAGE

- In a hermetically closed container.

DERIVED FORMS

- **Starting point.** Double aluminum and potassium sulphate ($AlK(SO_4)_2.12\ H_2O$).
- **Inert ingredient.** Lactose.
- **Method.** *Hahnemannian Method* **(11.1)**, Korsakovian Method **(11.2)**, *Streaming Method* **(11.3)**.
- **Dispensation.** From 2 DH trit. and 1 CH trit.
- **Packaging and storage.** In a neutral, amber and tightly closed container.

This translation does not replace the portuguese version.

AMMONIUM CARBONICUM

- $NH_4HCO_3.NH_4CO_2NH_2$; 157,12 [*10361-29-2*]
- Consists in a mix of ammonium bicarbonate (NH_4HCO_3) and ammonium carbamate (NH4CO2NH2) in several proportions. Contains, at least, 30% and, at most, 34% of NH3.

HOMEOPATHIC SYNONYM
- Ammonii carbonas, Carbonas ammonii.

CHEMICAL NAME
- Ammonium carbonate.

DESCRIPTION
- **Physical features.** White, translucent, hard mass with strong ammoniacal odor, or prismatic, small and white crystals. When exposed to air, there is a loss of ammonia and carbon dioxide, becoming opaque and converting in a porous and friable mass, of ammonium bicarbonate.
- **Solubility.** Soluble in water and slightly soluble in ethanol.
- **Incompatibilities.** Acids and acid salts, zinc and iron salts, alkaloid and calomel, alum and sodium and potassium tartrate.

IDENTIFICATION
A. Heated, it volatizes without carbonization, providing alkaline vapors to red litmus paper.
B. With 2 mL of sample's aqueous solution at 1% (p/v) add five drops of hydrochloric acid. Effervescence with gaseous detachment is observed.

PURITY TESTS
- **Chlorides (5.3.2.1) FB 5.** Prepare the solutions described below.
  - *Standard preparation*: add 1 mL of hydrochloric acid 0,01 *M* in 50 mL of purified water.
  - *Sample preparation*: dissolve 10 g of sample in approximately 25 mL of purified water and reduce the volume, in boiling water bath, till approximately 10 mL.
  - *Procedure*: develop, concurrently, *Standard preparation* and *Sample Preparation*. Add in both 30 mL of purified water, 5 mL of nitric acid 2 *M*, 1 mL of silver nitrate 0,25 *M* and complete the volume for 50 mL with water. Let it rest approximately for 10 minutes. The turbidity developed for *Sample preparation* must not be more intense than the *Standard preparation*'s. At most, 0,0035% (35 ppm).
- **Iron (5.3.2.4) FB 5.** Dissolve 5 g of the sample in approximately 50 mL of purified water and heat the boiling till it reduces the volume by 10 mL. Let it cool down and neutralize with diluted acetic acid. Proceed as described in *Iron limit rehearsal*. At most, 0,002% (20 ppm).
- **Heavy metals (5.3.2.3) FB 5.** Use *Method 1*. Volatize 1g of the sample in water bath, add to residue 1 mL of hydrochloric acid *M* and evaporate to dryness in water bath. Dissolve the residue in approximately 30 mL of water. Proceed as described in *Limit for heavy metals rehearsal*. At most 0,001% (10 ppm).
- **Sulphates (5.3.2.2) FB 5.** Prepare the solutions described below.
  - *Sample preparation*: dissolve 10 g of sample in approximately 25 mL of purified water and reduce the volume in water bath till approximately 10 mL.
  - *Standard preparation*: 2,5 mL of sulphuric acid 0,005 M in 50 mL of purified water.
  - *Procedure*: develop, concurrently, *Standard preparation* and *Sample Preparation*. Add in both 30 mL of purified water, 5 mL of hydrochloric acid 3 *M*, 1 mL of barium chloride

M. Complete the volume for 50 mL with water and heat in water bath for 15 minutes. The turbidity developed for *Sample preparation* must not be more intense than the *Standard preparation*'s. At most 0,012% (120 ppm).

- **Sulphated ash.** In previously tared capsule, calcine, carefully, 10 g of the sample. The residue must weigh, at most, 0,005 g (0,05%).
- **Thiocyanate.** Dissolve 0,5 g in 10 mL of purified water, slightly acidify with nitric acid 2 *M* and add 0,5 mL of ferric chloride SR. The mix must not become pink or red.

ASSAY

- Weigh 2,5 g of the sample, transfer to a volumetric flask of 500 mL and complete the volume with purified water. Stir till dissolution. Remove a aliquot of 25 mL of the previously prepared solution, add methyl orange SI or bromophenol blue SI (or a mix of both) and titrate with hydrochloric acid 0,1 *M*. The volume of consumed acid (x mL) corresponds to the total of carbonate (CO_3^{2-}) and bicarbonate (HCO_3^-). To determine the content of carbonate and bicarbonate, separately, remove a new aliquot of 25 mL of the ammonium carbonate solution, add phenolphtalein SI or mix of thymol blue and cresol red and titrate with hydrochloric acid 0,1 *M*. With this indicators, the existing carbon is semi-neutralized till it becomes bicarbonate. This way, the volume of spent acid (y mL) corresponds to half of the carbonate present in the sample. So: 2y = carbonate and x-2y = bicarbonate.

PACKAGING AND STORAGE

- In a neutral glass, amber, hermetically closed container, safe from light and less than 30 °C temperature.

DERIVED FORMS

- **Starting point.** Ammonium carbonate ($NH_4HCO_3.NH_4CO_2NH_2$).
- **Inert ingredient.** Lactose.
- **Method.** *Hahnemannian Method* **(11.1)**, Korsakovian Method **(11.2)**, *Streaming Method* **(11.3)**.
- **Dispensation.** From 2 DH trit. and 1 CH trit.
- **Packaging and storage.** In a neutral, amber and tightly closed container.

AMMONIUM MURIATICUM

- NH_4Cl; 53,49 [*12125-02-9*]
- Contains, at most, 99.5% of NH_4Cl, when desiccate over sulphuric acid for 24 hours.

HOMEOPATHIC SYNONYM
- Ammonium chloridum, Ammonium hidrochoridum, Ammonium chloratum.

CHEMICAL NAME
- Ammonium chloride.

DESCRIPTION
- **Physical-chemical characteristics.** White, crystalline or grainy powder, or colorless, hard and transparent crystals. Odorless, saline and refreshing flavor. Slightly hygroscopic. Sublimate directly without fusion.
- **Solubility.** Soluble in water, boiling water and slightly soluble in ethanol.
- **Incompatibilities.** With alkalies, lead and silver salts and earth alkaline carbonates.

IDENTIFICATION

A. Heat 0,1 g of ammonium chloride with 1 mL of aqueous solution of sodium hydroxide at 10% (p/v). Detachment of ammonia vapors is observed, this makes the red litmus paper, previously moistened, become blue.

B. With 2 mL of aqueous solution of ammonium chloride at 5% (p/v), add five drops of aqueous solution of silver nitrate at 1% (p/v). A white precipitate is produced, wich is soluble in many drops of ammonium hydroxide.

PURITY TESTS
- **Free acidity.** Prepare the *Solution (1)* described below. Remove a aliquot of 5 mL from the *Solution*
- *(1)*, add 0,2 mL of methyl red SI. To neutralize this solution it will be necessary, at most, 0,1 mL of sodium hydroxide 0,05 *M*.
- *Solution (1):* dissolve 11g of the sample in purified water and complete the volume for 55 mL using the same solvent.
- **Thiocyanate.** Remove a aliquot of 5 mL from *Solution (1)*, describes in *Free acidity*, add 2 mL of hydrochloric acid 3 *M* or nitric acid 2 *M* and 0,5 mL of ferric chloride 0,33 *M*. The liquid must not have pink or red coloring.
- **Arsenic (5.3.2.5) FB 5.** Remove a aliquot of 10 mL from *Solution (1)*, described in *Free acidity*, and proceed as described in *Limit for arsenic rehearsal*. At most, 0,0005% (5 ppm).
- **Iron (5.3.2.4) FB 5.** Remove a aliquot of 25 mL from Solution (1), described in *Free acidity*, and proceed as described in *Limit for iron rehearsal*. At most, 0,002% (20 ppm).
- **Heavy metals (5.3.2.3) FB 5.** Use *Method I*. Remove a aliquot of 5 mL from Solution (1), described in *Free acidity*, and proceed as described in *Limit for heavy metals rehearsal*. At most, 0.001% (10 ppm).
- **Sulphates (5.3.2.2) FB 5.** Prepare the solutions described below.
  - *Sample preparation*: dissolve 10 g of sample in approximately 25 mL of purified water and reduce the volume in water bath till approximately 10 mL.
  - *Standard preparation*: dissolve 2.5 mL of hydrochloric acid 0,005 *M* in 50 mL of purified water.

This translation does not replace the portuguese version.

  - *Procedure:* develop, concurrently, *Standard preparation* and *Sample Preparation*. Add in both 30 mL of purified water, 5 mL of hydrochloric acid 3 *M*, 1 mL of barium chloride 0,5 *M*. Complete the volume for 50 mL with water and heat in water bath for 15 minutes. The turbidity developed for *Sample preparation* must not be more intense than the produced in *Standard preparation*'s. At most, 0.012% (120 ppm).
- **Loss by desiccation (5.2.9) FB 5.** Desiccate over sulphuric acid, for 24 hours. At most, 0,5%.
- **Sulphated ash (5.2.10) FB 5.** In previously tared capsule, carefully calcine 10 g of the sample. At most 0,01%

ASSAY
- Dissolve 100 mg of the sample in 100 mL of purified water. Add i mL of dichlorofluorescein SI, mix and titrate with silver nitrate 0,1 *M* SV till all silver chloride flocculate and the mix acquires a
- light pink coloring. Each mL of silver nitrate 0,1 *M* SV corresponds to 5,35 mg de NH4Cl.

PACKAGING AND STORAGE
- In a neutral, amber and tightly closed glass container.

DERIVED FORMS
- **Starting point.** Ammonium chloride (NH4Cl).
- **Inert ingredient.** Ethanolic solution in different scales.
- **Method.** *Hahnemannian Method* **(11.1)**, Korsakovian Method **(11.2)**, *Streaming Method* **(11.3)**.
- **Dispensation.** From 1 DH trit. and 1 CH trit.
- **Packaging and storage.** In a neutral, amber and tightly closed container.

This translation does not replace the portuguese version.

AMMONIUM PHOSPHORICUM

- $(NH_4)_2HPO_4$; 132,07 [*7783-28-0*]
- Contains, at least, 96.0% and, at most, 102.0% of $(NH_4)_2HPO_4$.

HOMEOPATHIC SYNONYM
- Phosphas ammonicus, Ammonii phosphas.

CHEMICAL NAME
- Dibasic ammonium phosphate.

DESCRIPTION
- **Physical features.** Crystalline powder or crystals, white or almost white.
- **Solubility.** Easily soluble in water, practically insoluble in acetone and ethanol.

IDENTIFICATION
A. A solution of the sample at 5% (p/v) responds to the reactions of the potassium ion **(5.3.1.1) FB 5**.
B. A solution of the sample at 5% (p/v) responds to the reactions of the phosphate ion **(5.3.1.1) FB 5**.

PURITY TESTS
- **pH (5.2.19) FB 5.** 7,6 to 8,2. Set in aqueous solution at 1% (p/v).
- **Arsenic (5.3.2.5) FB 5.** Use *Spectrophotometric method*, *Method I*. Set in 1g of sample. At most 0,0003% (3 ppm).
- **Chlorides (5.3.2.1) FB 5.** Set in 1.22 g of sample. At most 0,03% (300 ppm).
- **Sulphates (5.3.2.2) FB 5.** Set in 0.8 g of sample. At most 0,15% (1500 ppm).
- **Heavy metals (5.3.2.3) FB 5.** Use *Method 1*. Dissolve 2 g of the sample in 25 mL of water. At most 0,001% (10 ppm).

ASSAY
- Dissolve 0.6 g of the sample in 40 mL of water. Titrate with sulphuric acid 0,05 *M* SV till pH 4.6, potentiometrically determined. Each mL of sulphuric acid 0,05 *M* SV corresponds to 13,206 mg of $(NH_4)_2HPO_4$.

DERIVED FORMS
- **Starting point.** Ammonium phosphate $(NH_4)_2HPO_4$.
- **Inert ingredient.** Lactose.
- **Method.** *Hahnemannian Method* **(11.1)**, Korsakovian Method **(11.2)**, *Streaming Method* **(11.3)**.
- **Dispensation.** From 1 DH trit. and 1 CH trit.
- **Packaging and storage.** In a neutral, amber and tightly closed container.

This translation does not replace the portuguese version.

ANACARDIUM ORIENTALE

- *Semecarpus anacardium* (L.) – ANACARDIACEAE

HOMEOPATHIC SYNONYM
- Anacardium, Anacardium latifolium, Anacardium officinarum, Anacardium tomentosa, Avicennia tomentosa, Semecarpus anacardium.

EMPLOYED PART
- Dry fruits.

PLANT DESCRIPTION
- *Semecarpus anacardium* L. is a evergreen tree with approximately 6 m of high, with numerous rough branches, of gray coloring. The leaves are alternate, with approximately 45 cm of length and 10 cm to 12 cm of width, complete, petiolate, glabrous. The flowers are small, of greenish-yellow coloring, with five sepals, five petals and five stamens. They present unilocular ovaries with three stylos.

DRUG DESCRIPTION
- The fruit, heart-shaped fleshy nut, yellow when dry is dark brown, presenting itself over pyriform receptacle of green coloring. It measures approximately 2 cm of length by 2 cm of width and approximately 0.5 cm od thickness. Contains light juice of reddish coloring, corrosive and resinous, with honey consistency and that darkens when dry and with air contact, is insoluble in water, it dissolves in ethanol at 90% (v/v) when in alkaline medium. The pericarp, rather developed, is enveloped by two coriaceous parts which cover the white almond enveloped by reddish skin.

PREPARATION OF MOTHER TINCTURE
- Proceed as described in *Preparations of mother tincture with plant origin* **(10.1)**. The mother tincture of *Anacardium orientale* is prepared via maceration or percolation, in a way that the alcoholic strength, during and by the end of the extraction, is of 90% (v/v).

MOTHER TINCTURE CHARACTERISTICS
- Liquid of reddish coloring, without a characteristic odor, of spicy and astringent flavor.

IDENTIFICATION
A. With 1 mL of mother tincture, add 1 mL of purified water. A clouding of the medium is observed, there may be a precipitation after some minutes.
B. With 5 mL of mother tincture, add ten drops of hydrochloric acid at 1% (p/v). Change of coloring must not occur.
C. With 1 mL of mother tincture, add 1 mL of ammonium hydroxide. An intense greenish-blue coloring is developed, with precipitation after approximately 5 minutes.
D. With 1 mL of mother tincture, add 1 mL of ethanol at 50% (v/v) and some drops of ferric chloride at 10% (p/v). A dark purple coloring is developed.
E. In a test tube, add 1 mL of mother tincture. Add, subsequently, ten drops of formed reagent, at the time of use, by equal parts of ferric chloride at 1% (p/v) and of potassium ferricyanide at 1% (p/v). A green coloring is developed.

This translation does not replace the portuguese version.

F. In a test tube, add 1 mL of mother tincture. Add ten drops of ninhydrin at 1% (p/v). Next, heat in boiling water bath for approximately 1 minute. A purple-blue coloring is developed.

G. Proceed as described in *Thin-layer chromatography* **(5.2.17.1) FB 5**, using silica gel G, as support, and mix of chloroform and methanol (95:5) as mobile phase. Apply, to plate 20 μL of mother tincture. Develop a chromatogram in a route of 10 cm. Remove the plate, let it air-dry. Examine under ultraviolet light (365 nm). The chromatogram presents a succession of stains with brownish-yellow fluorescence, with Rf values close to 0.35 and 0.45, one other also with brownish-yellow fluorescence with Rf close to 0.75 and a last one with greenish-blue fluorescence with Rf close to 0.95. Nebulize the chromatoplate with solution of antimony chloride at 1% (p/v) in chloroform and heat the stove to a temperature between 100 °C and 105 °C for 5 minutes. Examine under natural light. The chromatogram presents a purple stain with Rf close to 0.30 and a succession of purple stains, with values of near Rf of 0.55 and 0.75.

Develop a second chromatogram, using silica gel G, with support, and mix chloroform and methanol (90:10) as mobile phase. Apply to plate 20 μL of mother tincture. Develop a chromatogram in a route of 10 cm. Remove the plate, let it air-dry. Examine under ultraviolet light (365 nm). The chromatogram presents three stains with purple fluorescence and Rf values close to 0.60; 0.88; 0.93 and a fourth, with blue fluorescence and with Rf value close to 0.96. Next, place the same plate in vat containing iodine crystals, previously saturated with the developer vapors; let it in exposure till the total revelation. Six stains are observed, with Rf values, respectively, close to 0.43; 0.68; 0.80; 0.88; 0.93 and 0.96.

PURITY TESTS

- **Title in ethanol.** Must be between 85% and 95% (v/v).
- **Dry residue.** Must be 1,5% (p/v) or higher.

PACKAGING AND STORAGE

- In a neutral glass, amber container, safe from light and heat.

DERIVED FORM

- **Starting point.** Mother tincture.
- **Inert ingredient.** From 1 CH to 3 CH or 1 DH to 6 DH, use the same alcoholic strength of mother tincture. For other dynamizations, follow the general rule of preparation of derived pharmaceutical forms.
- **Method.** *Hahnemannian Method* **(11.1)**, Korsakovian Method **(11.2)**, *Streaming Method* **(11.3)**.
- **Dispensation.** From 1 CH or 2 DH, following the general rule of dispensation.
- **Packaging and storage.** In a neutral glass, amber, tightly close container, safe from light and heat.

This translation does not replace the portuguese version.

ANILINUM

- $C_6H_5NH_2$; 93,13 [*62-53-3*]
- Contains, at least, 99,0% of $C_6H_5NH_2$.

HOMEOPATHIC SYNONYM
- Phenylamine.

CHEMICAL NAME
- Phenil-amina.

DESCRIPTION
- **Physical features.** Oily, colorless or yellowish liquid, when recently distilled. Darkens when exposed to light and air. Characteristic odor and ardent flavor. Is volatile.
- **Solubility.** Slightly soluble in water, miscible with ethanol, ethyl ether and chloroform.

Physical-chemical constants.
- *Relative density* **(5.2.5) FB 5:** 1.02 to 25 °C.
- *Refractive Index* **(5.2.6) FB 5**: 1.5863.

IDENTIFICATION

A. The sample solution containing 5 g/mL in ethanol must present absorption spectrum on ultraviolet **(5.2.14) FB 5**, similar to aniline spectrum SQR, equally prepared. Maximum peaks are observed in approximately 235 nm to 286 nm.

B. Mix four to five drops of purified water at 0.5 mL of aniline, add five drops of sulphuric acid. Add two drops of potassium dichromate SR and five to ten drops of sulphuric acid till a greenish-blue coloring appears. Add, drop by drop, solution of calcium hypochlorite or of sodium hypochlorite. A purple-blue coloring is developed.

C. Diazotization test: dissolve 10 mL of the sample in enough quantity of hydrochloric acid 2. *M*. Put a drop of this solution in a touch plate and add a drop of sodium nitrate at 1% (p/v) and one drop of 2-naftol in sodium hydroxide 2 *M*. A reddish-orange coloring is developed.

D. Proceed as described in *Thin-layer chromatography* **(5.2.17.1) FB 5**, using silica gel G, as support; and mix of ammonia and methanol (1.5:100) as mobile phase. Let the vat saturating for 1 hour. Apply, separately, to the plate 10 µL of each of the solutions, recently prepared, described hereinafter.
  - *Sample solution*: sample solution at 1% (v/v) in acetic acid.
  - *Standard solution*: aniline solution SQR at 1% (v/v) in acetic acid.
- Develop a chromatogram in a route of 10 cm. Remove the plate, let it air-dry. Examine under ultraviolet light (254 nm) or use solution of potassium permanganate at 1% (p/v) as developer. The aniline must present Rf close to 0.72.

PURITY TESTS
- **pH (5.2.19) FB 5.** An aqueous solution at 0,2 *M* presents pH 8.1.
- **Sulphated ash (5.2.10) FB 5.** Evaporate in chapel 20 mL and calcine at 800 °C for 15 minutes. The residue must not weigh, at most, 1 mg (0,005%).
- **Hydrocarbon and nitrobenzene.** With 5 mL of sample add 10 mL of hydrochloric acid. The solution is clear while hot and must remain this way after dilution with 15 mL of purified water.

This translation does not replace the portuguese version.

ASSAY

- Dissolve 0,4 g of the sample in 50 mL of glacial acetic acid and titrate with perchloric acid 0,1 *M* SV, using 1-naftolbenzeine SI as indicator. Each mL of perchloric acid 0,1 *M* SV corresponds to 0,009313 g of aniline.

PACKAGING AND STORAGE

- In a dark container safe from light, preferably enveloped by a dark paper or aluminum paper and hermetically closed.

DERIVED FORM

- **Starting point.** Phenyl-amina ($C_6H_5NH_2$).
- **Inert ingredient.** Ethanol at 90% (v/v) for 1 DH and 1 CH, ethanol in different scales for the following.
- **Method.** *Hahnemannian Method* **(11.1)**, Korsakovian Method **(11.2)**, *Streaming Method* **(11.3)**.
- **Dispensation.** From 4 DH or 2 CH.
- **Packaging and storage.** In a neutral, amber and tightly closed container.

This translation does not replace the portuguese version.

APIS MELLIFICA

- *Apis mellifica* (L.) – APIDAE

HOMEOPATHIC SYNONYM
- Apis.

EMPLOYED PART
- Live bees.

INSECT DESCRIPTION
- *Apis mellifica* L. is an insect of black coloring with silky shine, slightly pubescent, measuring 12 mm to 20 mm of length. The abdomen is voluminous, marked by yellow stripes. The thorax presents hair, is equipped with two pairs of uneven wings that cover the insect entirely, keeping itself horizontally when resting. The head, triangular, presents oral system with a tube, lip palps and two antennas. The thorax is formed by three closely linked segments. On the thorax inferior part, three pairs of paws are inserted. The posterior paws are equipped with two special systems (like a basket) with hair over the tibia as bristles where the pollen collected from the plants is accumulated. The abdomen, striped and penducular, is formed by twelve rings, and only six of those are visible. Only the females (workers) present sting placed on the terminal posterior part of the abdomen, which is connected to the venom bag.

DRUG DESCRIPTION
- The drug, formed by female insects, present the macroscopic characters previously described.

PREPARATION OF MOTHER TINCTURE
- The mother tincture of *Apis mellifica* L. is prepared from live bees placed on a glass flask and irritated by stirring for the maximum liberation of venom. Next, proceed as described in
- *Preparation of mother tincture of animal origin* **(10.2)** applying ethanol at 65% (v/v).

MOTHER TINCTURE CHARACTERISTICS
- Pale yellow liquid, with slightly accentuated odor and flavor.

IDENTIFICATION
A. With 1 mL of mother tincture, add 1 mL of alkaline cupric citrate SR. Heat till boiling. A rusty coloring is developed followed by precipitate of same color.
B. With 1 mL of mother tincture, add 1 mL of alkaline cupric tartrate SR. After heating, a rusty coloring is developed followed by formation of precipitate of same color.
C. With 1 mL of mother tincture, add 1 mL of Tollens reagent. Heat till boiling. A black precipitate is developed, and it could reach to formation of silver mirror.
D. With 1 mL of mother tincture, add some drops of ninhydrin solution at 0.1% (p/v). Heat till boiling. A purple-blue coloring is developed.
E. Proceed as described in *Thin-layer chromatography* **(5.2.17.1) FB 5**, using silica gel G, as support, and mix of ethanol and water (63:17) as mobile phase. Apply, to plate, 30 μL of mother tincture. Develop a chromatogram in a route of 10 cm. Remove the plate and let it air-dry. Examine under ultraviolet light (365 nm). The chromatogram presents, usually, four to five stains with blue fluorescence and with Rf values between 0.60 and 0.90. Nebulize the plate with ninhydrin solution at 0.1% (p/v). Heat in stove in a temperature between 100

This translation does not replace the portuguese version.

°C and 105 °C, for 10 minutes. Examine under natural light. The chromatogram presents intense ocher stain with Rf close to 0.80.

PURITY TESTS
- **Title in ethanol.** Must be between 60% and 70% (v/v).
- **Dry residue.** Must be 0,25% (p/v) or higher.

PACKAGING AND STORAGE
- In a neutral glass, amber, tightly close container, safe from light and heat.

DERIVED FORM
- **Starting point.** Mother tincture.
- **Inert ingredient.** From 1 CH to 3 CH or 1 DH to 6 DH, use the same alcoholic strength of mother tincture. For other dynamizations, follow the general rule of preparation of derived pharmaceutical forms.
- **Method.** *Hahnemannian Method* **(11.1)**, Korsakovian Method **(11.2)**, *Streaming Method* **(11.3)**.
- **Dispensation.** From mother tincture, following the general rule of dispensation.
- **Packaging and storage.** In a neutral glass, amber, tightly close container, safe from light and heat.

This translation does not replace the portuguese version.

ARGENTUM METALLICUM

- Ag; 107,9 [*7440-22-4*]
- Contains, at least 99.0% taking as a reference the dry substance inn constant weight at 105 °C.

HOMEOPATHIC SYNONYM
- Argentum foliatum, Argentum.

CHEMICAL NAME
- Metallic silver.

DESCRIPTION
- **Physical features.** Grayish-white metal, bright, malleable and ductile. Doesn't oxidize with air contact. Darkens under sulphidric gas action.
- **Solubility.** Insoluble in water and ethanol.
- **Melting point (5.2.2) FB 5.** 960,5 °C.

IDENTIFICATION

A. Weigh 0.1 g of metallic silver and treat with enough quantity of aqueous solution of nitric acid 8 till complete dissolution. If necessary, reduce the volume by heating and dilute qith enough quantity of purified water to obtain the volume of 10 mL of the solution (*Solution A*). This solution responds to the reactions of silver ion **(5.3.1.1) FB 5**.

B. With 2 mL of *Solution A*, described in test **A**. of *Identification*, add five drops of aqueous solution of hydrochloric acid at 1% (p/v). The formation of white precipitate is observed, which dissolves itself by addition of drops of aqueous solution of ammonium hydroxide (1:1). Next, add drops of aqueous solution of nitric acid at 1% (v/v). The formation of white precipitate is observed.

C. Repeat the test B. of Identification and treat 1 mL of the obtained solution with aqueous solution of potassium iodate at 1% (p/v). The formation of yellow precipitate is observed.

PURITY TESTS
- **Acidity or alkalinity.** Mix, with stirring, 0.05 g of powder silver, with 10 mL of purified water. Heat till boiling, for 5 minutes. Filter while hot. Cool down. With 2 mL of filtrate, add three drops of bromothytol blue SI and 0.1 mL of aqueous solution of hydrochloric acid 0.02 *M*. A yellow coloring is developed. Add 0.15 mL of aqueous solution of sodium hydroxide 0.02 *M*. The change from yellow to blue coloring is observed.
- **Metallic impurities.** With 5 mL of *Solution A*, described in test **A.** of *Identification*, add 20 mL of purified water and 7.5 mL of aqueous solution of hydrochloric acid at 5% (v/v). Filtrate. Evaporate 10 mL of the filtrate in boiling water bath, till it dries. Dry it in a stove between 100 °C and 105 °C till constant weight. The residue must not be higher than 0.0001g.

ASSAY
- Dissolve 0.32 g of the metal, in enough quantity of aqueous solution of nitric acid 8 *M*, squaring the valume in 50 mL by dilution with purified water or reduction, when necessary. Titrate with potassium thiocyanate 0,1 *M* SV, using aqueous solution of ammoniacal ferric sulphate at 1% (p/v) as a indicator. Each mL of consumed potassium thiocyanate 0,1 *M* SV corresponds to 0,01079 g of metallic silver.

This translation does not replace the portuguese version.

PACKAGING AND STORAGE

- In hermetically closed containers, safe from humidity and gases.

DERIVED FORMS

- **Starting point.** Metallic silver (Ag).
- **Inert ingredient.** Lactose.
- **Method.** *Hahnemannian Method* **(11.1)**, Korsakovian Method **(11.2)**, *Streaming Method* **(11.3)**.
- **Dispensation.** From 3 DH trit. and 2 CH trit.
- **Packaging and storage.** In a neutral, amber and tightly closed container.

This translation does not replace the portuguese version.

ARGENTUM NITRICUM

- $AgNO_3$; 169,9 [*7761-88-8*]
- Contains, at least, 99.0% and at most, 100.5% of $AgNO_3$, relating to the dry substance.

HOMEOPATHIC SYNONYM
- Azotas argenticus, Nitras argenti, Nitrus argenticus.

CHEMICAL NAME
- Silver nitrate.

DESCRIPTION
- **Physical features.** Large colorless, transparent crystals or little white crystals.
- **Solubility.** Highly soluble in water, soluble in ethanol, slightly soluble in ammoniacal water and ethyl ether, little soluble in acetone.

Physical-chemical constants.
- *Melting point* **(5.2.2) FB 5**: 212 °C.

IDENTIFICATION
A. With 10 mL of sample solution at 10% (p/v), add five drops of diphenylamina SR and homogenize. Carefully, pour the solution for test tube containing 2 mL of sulphuric acid, A blue coloring is developed on the interface,
B. The solution at 2% (p/v) responds to the reactions of the silver ion **(5.3.1.1) FB 5**.
C. The solution at 2% (p/v) responds to the reactions of the nitrate ion **(5.3.1.1) FB 5**.

PURITY TESTS
- **Solution aspect.** The aqueous solution at 10% (p/v) is clear **(5.2.25) FB 5** and colorless **(5.2.12) FB 5**.
- **Acidity or alkalinity.** With 2 mL of solution at 4% (p/v), add 0.1 mL of bromocresol green SI. A blue coloring is developed. With 2 mL of solution at 10% (p/v), add 0.1 mL of phenol red SI. It develops a yellow coloring.
- **Aluminum, coper, lead and bismuth.** Dissolve 1 g of the sample in mix of 4 mL of ammonia 13,5 *M* and 6 mL of water. The solution is clear **(5.2.25) FB 5** and colorless **(5.2.12) FB 5**.
- **Evaporation residue.** With 30 mL of solution at 4% (p/v), add 7,5 mL of diluted hydrochloric acid, stir vigorously, heat for 5 minutes in water bath and filtrate. Evaporate 20 mL of filtrate in water bath and desiccate the residue in stove, between 100 °C and 105 °C. At most 2 mg (0,3%).

ASSAY
- Previously desiccate the sample, over silica, for 4 hours, safe from light. Weigh, precisely, about 0.3 g of desiccated sample and dissolve in 50 mL of water. Add 2 mL of nitric acid, 2 mL of amoniacal ferric sulphate SR and homogenize. Titrate with ammonium thiocyanate 0,1 *M* SV till a reddish-yellow coloring. Each mL of ammonium thiocyanate 0,1 *M* SV corresponds to 16,987 mg of $AgNO_3$.

PACKAGING AND STORAGE
- In a neutral glass, dark container, safe from light, hermetically closed.

This translation does not replace the portuguese version.

DERIVED FORM

- **Starting point.** Silver nitrate (AgNO3).
- **Inert ingredient.** Hydroalcoholic solution in different scales.
- **Method.** *Hahnemannian Method* **(11.1)**, Korsakovian Method **(11.2)**, *Streaming Method* **(11.3)**.
- **Dispensation.** From 6 DH or 3 CH.
- **Packaging and storage.** In a neutral, amber and tightly closed container.

This translation does not replace the portuguese version.

ARNICA MONTANA

- *Arnica montana* (L.) – COMPOSITAE (ASTERACAE)

HOMEOPATHIC SYNONYM
- Arnica, Caltha alpina, Crysanthemum latifolum, Doronicum germanicum, Doronicum montanum.

EMPLOYED PART
- Whole plant dry.

PLANT DESCRIPTION
- *Arnica montana* L**.** is a herbaceous species, perennial, with thin rhizome, dark with 3 cm to 5 cm of length, which has numerous filiforms roots. The stem has 25 cm to 30 cm of height, rough and pubescent, erect, striped, presenting one or two pais of opposing branches. Present little leaves with 4 cm to 8 cm of length evolving the stem, opposed and obovate. The radical leaves are accumulated on the base, the superiors being smaller than the rest. The flower buds measure close to 6 cm of diameter, evolved by 20 to 24 bracts, disposed in two series. The bracts are narrow, spear-shaped, reaching 15 mm of length, with a complete bordo, of brownish-green coloring and short hair. The receptacle, when deprived of the flowers, is slightly convex, with approximately 1 cm of diameter, showing little cavities in which the flowers are inserted, presenting, still between the cavities, withe, short and hard hair. The ligulate flowers, in numbers of 14 to 20, are arranged on the receptacle's periphery, measuring up to 2.5 cm of length and are feminines, showing the infero-ovary, of 4 mm to 5 mm of length, brownish, with four to five gables slightly visible and short and white hair. The pappus is composed by a layer of yellowish bristles. The ligule, of orange-yellow coloring, measures up to 2 cm of length and presents three lobes and seven to fifteen ribbing on the base. The stylus is thin and is divided on the terminal region in two stigmas. The presence of staminodia is seen. The tube-shaped flowers are arranged on the central part of the receptacle, are hermaphrodites and more numerous. The ovary, the pappus and the stylus are similar to the ones of the ligulate flowers. The corolla, of approximately 0.5 cm of length, is tubular, flared on superior part, of orange-yellow coloring, with five lobes recurved to the outside and present externally, on the base, white hair. The antennas, in numbers of five, are gathered forming a tube. The pollen teaks are elliptical, roundish, and the connective is prolonged on a triangular piece.

DRUG DESCRIPTION
- According to the plant description.

PREPARATION OF MOTHER TINCTURE
- Proceed as described in *Preparations of mother tincture with plant origin* **(10.1)**. The mother tincture of *Arnica montana* is prepared by maceration or percolation, in a way that the alcohol strength during and by the end of the extraction is of 45% (v/v) according to the general technique of preparation of mother tincture.

MOTHER TINCTURE CHARACTERISTICS
- Liquid of yellowish-brown coloring and pleasant odor, slightly aromatic, bitter and ardent flavor.

This translation does not replace the portuguese version.

IDENTIFICATION

A. With 1 mL of mother tincture, add 10 mL of purified water. A formation of opalescence is seen, which becomes definitely yellow by addition of 0.1 mL of solution of sodium hydroxide at 1% (p/v).

B. With 2 mL of mother tincture, add some drops of ferric chloride solution at 10% (p/v). A green coloring is developed.

C. Evaporate 3 mL of mother tincture till it dries. Add to the residue, by the container walls, 0.2 mL of solution of sulphuric acid at 10% (p/v). It develops a purple coloring.

D. With 5 mL of mother tincture, add five drops of solution of sodium acetate at 1% (p/v). Add 0.2 mL of ethanolic solution of aluminum chloride 1% (p/v). It develops a yellow coloring.

E. Proceed as described in *Thin-layer chromatography* **(5.2.17.1) FB 5**, using silica gel G, as support, and mix of chloroform, glacial acetic acid, methanol and purified water (15:8:3:2) as mobile phase. Apply, separately to the plate, 40 µL of mother tincture and 5 µL of *Standard solution*, recently prepared, described below.

– *Standard solution:* dissolve 10 mg of caffeic acid in 10 mL of ethanol at 70% (v/v).

Develop a chromatogram in a route of 10 cm. Remove the plate, let it air-dry. Examine under ultraviolet light (365 nm). Regarding the chromatogram of the Standard solution a stain of blue fluorescence can be seen with Rf close to 0.75, while the chromatogram concerning the mother tincture presents, usually, two stains of greenish fluorescence with Rfs values close to 0.35 and 0.45, two stains with blue fluorescence with Rfs values close to 0.75 (caffeic acid) and 0.95, and a red stain next to the solvent line. Next, nebulize the chromatogram with solution of aminoethanol difenilborate at 1% (p/v). Examine under ultraviolet light (365 nm). Concerning the chromatogram of *Standard Solution*, a stain with green fluorescence can be see with Rf close to 0.75. While the chromatogram related to the mother tincture presents a stain with orange fluorescence with Rf close to 0.25, two greenish-yellow fluorescent stains with Rfs close to 0.35 and 0.45, another orange fluorescent stain with Rf close to 0.50 and a last green fluorescent stain with Rf close to 0.75 (caffeic acid).

Develop a second chromatogram, under the same previous conditions, nebulize the chromatoplate with anisaldehyde solution at 1% (p/v) and heat it between 100 °C and 105 °C for 10 minutes. Examine under natural light. The chromatogram presents two stains of irregular shape relatively well separated, with Rf close to 0.20, another stain with yellow fluorescence wtih Rf close to 0.50, another with light-yellow fluorescence and Rf close to 0.65, and several stains with purple fluorescence between Rf 0.85 and the solvent line.

PURITY TESTS

- **Title in ethanol.** Must be between 40% and 50% (v/v).
- **Dry residue.** Must be 1% (p/v) or higher.

PACKAGING AND STORAGE

- In a neutral glass, amber, tightly close container, safe from light and heat.

DERIVED FORM

- **Starting point.** Mother tincture.
- **Inert ingredient.** From 1 CH to 3 CH or 1 DH to 6 DH, use the same alcoholic strength of mother tincture. For other dynamizations, follow the general rule of preparation of derived pharmaceutical forms.

This translation does not replace the portuguese version.

- **Method.** *Hahnemannian Method* **(11.1)**, Korsakovian Method **(11.2)**, *Streaming Method* **(11.3)**.
- **Dispensation.** From 1 CH or 2 DH, following the general rule of dispensation.
- **Packaging and storage.** In a neutral glass, amber, tightly close container, safe from light and heat.

This translation does not replace the portuguese version.

AVENA SATIVA

- *Avena sativa* (L.) – GRAMINAE

HOMEOPATHIC SYNONYM
- Avena

EMPLOYED PART
- Aerial parts in flowering

PLANT DESCRIPTION
- *Avena sativa* L. is and annual species of fibrous, fascicular roots, of erect, cylindric, glabrous stem, it could reach 60 cm to one meter high. The leaves are alternated, flat, linear, lanceolate, invaginate, glabrous, of short ligule. The inflorescence in panicle is erect, pyramidal, with flowers approximately measuring 1 cm. The flowers are hermaphrodite and possess three stamen with moderately fixed anthers, containing a unilocular ovary, ciliated on crest and ceasing by two feathered stigmas. The bifid fruit is caryopsis elongated, pointy, of pale-yellow coloring.

DRUG DESCRIPTION
- The drug is composed by aerial partes in flowering.

PREPARATION OF MOTHER TINCTURE
- Proceed as described in *Preparations of mother tincture from dry plants* **(10.1.1).** The mother tincture of *Avena sativa* is prepared with ethanol at 65% (v/v) from the aerial parts in flowering of the vegetable, by maceration.

MOTHER TINCTURE CHARACTERISTICS
- Liquid of greenish-yellow coloring, practically odorless, of starchy flavor.

IDENTIFICATION
A. With 1 mL of mother tincture, add five drops of sodium hydroxides solution at 10% (p/v). It develops an intense yellow coloring.
B. With 2 mL of mother tincture, add five drops of Tollens reagent. Heat for 1 minute in boiling water bath. The formation of dark gray precipitate is observed.
C. With 2 mL of mother tincture, add five drops of alkaline cupric tartrate SR. It can be seen the formation, by cold, of yellow precipitate and the supernatant presents yellowish-green coloring.
D. With 1 mL of mother tincture, add a drop of ferric chloride solution at 10% (p/v). It develops a dark green coloring.
E. With 2 mL of mother tincture, add five drops of silver nitrate solution at 1% (p/v). Heat in boiling water bath for 2 minutes. The formation of dark precipitate is observed.
F. With 2 mL of mother tincture, add five drops of ninhydrin solution at 1% (p/v). Heat in boiling water bath for 2 minutes. It develops a purple coloring.
G. Proceed as described in *Thin-layer chromatography* **(5.2.17.1) FB 5**, using silica gel G, as support and mix of 1-butanol, water and acetic acid (40:10:10), as mobile phase. Apply, to plate, 20 μL of mother tincture. Develop a chromatogram in a route of 10 cm. Remove the plate, let it air-dry. Examine under ultraviolet light (365 nm). Usually, a stain of blueish

This translation does not replace the portuguese version.

coloring is seen with Rf close to 0.40, another one, brwon, with Rf close to 0.50 and a third one, reddish, with Rf close to 0.90. Next, nebulize the chromatogram with ethanolic solution of aluminum chloride at 1% (p/v). Examine under ultraviolet light (365 nm). The stain with Rf close to 0.50 appears with yellow coloring.

- Repeat the chromatogram employing mobile phase formed by the mix of chloroform, methanol and water (64:50:10). Develop a chromatogram in a route of 10 cm. Remove the plate, let it air-dry. Nebulize with vanillin solution at 1% (p/v) in sulphuric acid at 97% (p/p). Can be seen the appearance of approximately 16 stains with colors that range from gray to purple-red. Next, heat the plate for approximately 10 minutes in stove at 105 °C. All stains acquire brown-red coloring.

PURITY TESTS

- **Title in ethanol.** The title in ethanol must be between 60% and 70% (v/v).
- **Dry residue.** Must be higher than 0,6% (p/v).

PACKAGING AND STORAGE

- In a neutral glass, amber, hermetically closed container, safe from light and heat.

DERIVED FORM

- **Starting point.** Mother tincture.
- **Inert ingredient.** On the three first centesimal dinamizations and six first decimal, use the same alcoholic strength of the mother tincture.
- **Method.** *Hahnemannian Method* **(11.1)**, Korsakovian Method **(11.2)**, *Streaming Method* **(11.3)**.
- **Dispensation.** From 1 Ch and 1 DH it will be employed ethanol with the same ethanolic title of mother tincture, on the first three dinamizations for the centesimal scale and on the first ones for the decimal scale. Next, employ the hydroalcoholic solution at 30% (p/p).
- **Packaging and storage.** In a neutral glass, amber container, safe from light and heat.

This translation does not replace the portuguese version.

BARYTA CARBONICA

- $BaCO_3$; 197,35 [*513-77-9*]
- Contains, at least, 98% of $BaCO_3$, relative to the dry substance in stove at 105 °C, till constant weight.

HOMEOPATHIC SYNONYM
- Barii carbonas, Baryta, Barium carbonicum.

CHEMICAL NAME
- Barium carbonate.

DESCRIPTION
- **Physical-chemical characteristics.** White powder, of high density, odorless and tasteless. Easily decomposable in acid medium, with liberation of carbon dioxide. Decompose itself at 1300 °C, detaching carbon dioxide.
- **Solubility.** Little soluble in water, soluble in hydrochloric acid and in diluted nitric acid. Insoluble in ethanol.
- **Incompatibilities.** With inorganic acids and acetic acid.

IDENTIFICATION
A. A small quantity of the sample, dampened with hydrochloric acid SR, carried in platinum strap to the non-illuminating zone of Bunsen burner, a light-green coloring is developed.
B. With 2 mL of sample's aqueous solution at 0.05% (p/v), add five drops of hydrochloric acid. Effervescence with gaseous detachment is observed.
C. With 0.5 g of sample, add 5 mL of nitric acid. Heat till boiling. Let it cool down. Dilute with enough quantity of purified water. Filtrate. With the filtrate, add five drops of aqueous solution of sulphuric acid at 5% (v/v). The formation of white precipitate is observed.

PURITY TESTS
- **Calcium.** With 2 mL of sample's aqueous solution at 2% (p/v), add 5 mL of nitric acid. Add, next, 5 mL of ammonium hydroxide and five drops of aqueous solution of oxalic acid at 1% (p/v). Doesn't develop turbidity nor precipitation.
- **Chlorides.** With 2 mL of aqueous solution of sample at 20% (p/v), add 5 mL of nitric acid, 20 mL of purified water and five drops of aqueous solution of silver nitrate at 1% (p/v). Doesn't develop turbidity nor precipitation.

ASSAY
- Weigh 197,3 mg of the sample, add to a volumetric flask of 100 mL and complete the volume with purified water. Remove a aliquot of 25 mL of this solution and dilute with approximately 100 mL of purified water. Adjust the pH of the solution to 12.0 by adding 3 mL to 6 mL of sodium hydroxide solution *M*. The pH must be controlled with a potentiometer, because it must be between 11.5 and 12.7. Add 30 mg to 50 mg of a solid mix of thymol blue indicator at 1% (p/p) in potassium nitrate and titrate with disodium edetate 0,01 *M* SV till the color changes from blue to gray. Each mL of disodium acid 0,01 *M* SV corresponds to 1,973 mg of $BaCO_3$.

This translation does not replace the portuguese version.

PACKAGING AND STORAGE

- In a neutral, amber and hermetically closed container.

DERIVED FORM

- **Starting point.** Barium carbonate ($BaCO_3$).
- **Inert ingredient.** Lactose.
- **Method.** *Hahnemannian Method* **(11.1)**, Korsakovian Method **(11.2)**, *Streaming Method* **(11.3)**.
- **Dispensation.** From 6 DH trit. or 3 CH trit.
- **Packaging and storage.** In a neutral, amber and tightly closed container.

This translation does not replace the portuguese version.

BARYTA IODATA

- $BaI_2.2H_2O$; 427,18 [7787-33-9]
- Contains, at least, 98% and at most, 102% of BaI_2, relating to the anhydrous substance.

HOMEOPATHIC SYNONYM
- Barium iodatum, Baryta hidroiodica, Barii iodidum, Barii iodurum.

CHEMICAL NAME
- Barium iodate.

DESCRIPTION
- **Physical-chemical characteristics.** Spiky crystals or crystalline prisms, colorless, deliquescent, odorless, or white granules that become reddish with air contact with iodine liberation. *Relative density* **(5.2.5) FB 5**: approximately 5,15 g/mL at 20 °C.
- **Solubility.** Easily soluble in water, soluble in ethanol and acetone.
- **Incompatibilities.** Inorganic acids, alkalis, alkaline carbonates, alkaline phosphates, soluble oxalates, alumen, sodium borate.

IDENTIFICATION
A. A small quantity of the sample, dampened with hydrochloric acid, carried in platinum strap to the non-illuminating zone of Bunsen burner flame, prints a light-green coloring to itself.
B. The sample solution at 1% (p/v) is neutral or slightly alkaline.
C. With 2 mL of the sample solution at 5% (p/v) add 10 drops of sulphuric acid solution at 5% (p/v). Can be seen a formation of white precipitate insoluble in diluted hydrochloric acid and nitric acid.
D. With 5 mL of the sample solution at 5% (p/v) add some milligrams of sodium nitrite and 0.5 mL of acetic acid. Stir till complete dissolution. Add 1 mL of carbon tetrachloride. Stir vigorously. The phase correspondent to the carbon tetrachloride acquires a purple coloring.

PURITY TESTS
- **Solution aspect.** The *Solution (1)* described below is clear **(5.2.25) FB 5**.
- *Solution (1)*: dissolve 1 g of the sample in 100 mL of purified water.
- **Alkalinity.** Dissolve 4 g of the sample in 20 mL of purified water and add 0.05 mL of bromothymol blue SI. To reach the turning point of the indicator, it must not be necessary more than 0.2 mL of hydrochloric acid 0,01 *M*.
- **Chlorides (5.3.2.1) FB 5.** With 10 mL of the *Solution (1)*, described in *Solution aspect*, proceed as described in *Limit for chlorides rehearsal*. At most 0,01% (100 ppm).
- **Iodates.** With 10 mL of *Solution (1)*, described in *Solution aspect*, add 0.25 mL of starch solution at 1% (p/v) and 0.2 mL of sulphuric acid at 1% (p/v). Let it rest safe from light for 2 minutes. The solutions remains unchanged, not developing blue or purple coloring.

ASSAY
- Dissolve 0.2 g of the sample, weighed with accuracy of 1 mg, in solution of hydrochloric acid at 0,5% (v/v) in purified water. Add 100 mL of methanol 10 mL of ammonium hydroxide and 2 mg of ftaleine purple. Titrate with disodium edetate 0,05 *M* SV till it changes from purple to colorless.
- Each mL of disodium edetate 0,05 M SV corresponds to 0,021 g of $BaI_2.2H_2O$.

This translation does not replace the portuguese version.

PACKAGING AND STORAGE

- In a neutral glass, amber, tightly close container, safe from light and heat.

DERIVED FORM

- **Starting point.** Iodate of dihydrated barium ($BaI_2.2H_2O$).
- **Inert ingredient.** Use ethanol at 70% (v/v) till 3 CH or 6 DH and for the rest, follow the general rule of preparation of derived pharmaceutical forms.
- **Method.** *Hahnemannian Method* **(11.1)**, Korsakovian Method **(11.2)**, *Streaming Method* **(11.3)**.
- **Dispensation.** From 3 CH or 6 DH, following the general rule of dispensation.
- **Packaging and storage.** In a neutral glass, amber, tightly close container, safe from light and heat.

This translation does not replace the portuguese version.

BARYTA MURIATICA

- $BaCl_2.2H_2O$; 244,28 [*10326-27-9*]
- Contains, at least, 99% and, at most, 100.55% of $BaCl_2.2H_2O$.

HOMEOPATHIC SYNONYM
- Barita muriatica, Baryum muriaticum, Baryum chloratum.

CHEMICAL NAME
- Barium chloride.

DESCRIPTION
- **Physical features.** Crystals, granules or translucent powder, odorless. Looses crystallization water at 120 °C.
- **Solubility.** Soluble in water and methanol. Insoluble in ethanol, acetone and ethyl acetate.
- **Incompatibilities.** With silver nitrate.

IDENTIFICATION

A. A small quantity of the sample, dampened with hydrochloric acid, carried in platinum strap to the non-illuminating zone of Bunsen burner flame, develops a light-green coloring to itself.

B. Prepare aqueous solution of barium chloride at 5% (p/v). With 2 mL of this solution, add five drops of aqueous solution of sulphuric acid at 5% (v/v). The formation of white precipitate is observed.

C. Prepare aqueous solution of barium chloride at 5% (p/v). With 2 mL of this solution, add five drops of aqueous solution of silver nitrate at 1% (p/v). It can be seen the formation of white precipitate, soluble in excess of ammonium hydroxide.

PURITY TESTS
- **Lead.** Dissolve 1g of the sample in 40 mL of purified water recently boiled and cooled, add 5 mL of acetic acid free of lead and render the mix alkaline with sodium sulphide SR, also free of lead. At most, a soft coloring should be produced.
- **Nitrate.** Dissolve 1 g of sample in 10 mL of purified water, add 1 mL of carmine indigo SR and 10 mL of sulphuric acid free of nitrogen and heat till it boils. The blue coloring doesn't disappears completely.
- **Loss by desiccation (5.2.9) FB 5.** Looses, at least, 14% and, at most, 16% of its weight when submitted to drying in stove at 120 °C, till constant weight.

ASSAY
- Dissolve 0.5 g of barium chloride, n 50 mL of purified water in flask with lid, add 10 mL of nitric acid, 50 mL of silver nitrate 0,1 *M*, 3 mL of nitrobenzene and vigorously stir the mix for 1 minute. Titrate the excess of silver nitrate with ammonium thiocyanate 0,1 *M* SV using, as indicator, ammoniacal ferric sulphate SR. Stir well during the additions of the tritant solution. Each mL of silver nitrate 0,1 *M* corresponds to 0,01221 g of $BaCl_2.2H_2O$.

PACKAGING AND STORAGE
- In a hermetically closed container, safe from heat (avoid storage in high temperatures).

This translation does not replace the portuguese version.

DERIVED FORM

- **Starting point.** Barium chloride (BaCl2.2H2O).
- **Inert ingredient.** Lactose.
- **Method.** *Hahnemannian Method* **(11.1)**, Korsakovian Method **(11.2)**, *Streaming Method* **(11.3)**.
- **Dispensation.** From 6 DH trit. or 3 CH trit.
- **Packaging and storage.** In a neutral, amber and tightly closed glass container.

This translation does not replace the portuguese version.

BELLADONNA

- *Atropa belladonna* (L.) – SOLANACEAE

HOMEOPATHIC SYNONYM
- *Atropa belladonna, Solanum furiosum, Belladonna bacifera.*

EMPLOYED PART
- Whole blooming plant.

PLANT DESCRIPTION
- *Atropa belladonna* L. is a perennial plant with fusiform fleshy root preenting numerous ramifications of brown coloring. Could reach up to 2 m high. Is lignified at the base, branched presenting glandulous hair. The leaves are alternated, simple, elliptical, oval-lanceolate to largely oval, comlete, of acuminated apex, attenuated, simetric base and decurrent, and complete bordo. Measure 5 cm to 25 cm of length and 3 cm to 12 cm of width, with petiole of 0.5 cm to 4 cm. The coloring goes from green to greenish-brown, being darker on the superior face. The dry leaves are wrinkled, friable and thin. The young leaves are pubescent, however the older are only slightly pubescent over the ribbing and petiole. The venation is peninervea, the lateral ribbing start in the median ribbing on an angle of approximately 60° and anastomose close to the edge. The surface of the leave is dry and rough to touch, due to the presence of cells with microcrystalline content of calcium oxalate in the mesophyll. This cells appear as tiny shinning dots, when the surface is illuminated; the other cells contract more during the desiccation. The examination through magnifying glass shows the same dark dots by transparency and shinning by reflection. The blooming luminaries present hollow and flatten stem, in which are inserted germinated leaves, of uneven size, on whose axilla are located solitary flowers. The flowers possess persistent chalice, gamosepals, of 5 triangular lobes; the corolla is campanulate, purple to yellowish-brown, with five small lobes facing the exterior. The corolla measures up to 2.5 cm of length by 1.2 cm of high. The androceu has five epipetall stamen. The gineceu has a biocular upper ovary, with numerous seminal rudiments. The fruit is subglobular, from green to brown or dark-purple coloring, with up to 1.2 cm of diameter and persistent chalice. The fruit, when ripe, contains numerous seeds of dark-brown coloring and reniforms.

DRUG DESCRIPTION
- The drug is composed by leaves and flowers with wavy aspect.

MICROSCOPIC DESCRIPTION
- The leave presents epidermis unistratified with cells of round or elongated outline on periclinal direction, with sinuous anticline walls, of thin cuticle and finely stripped. Tector and glandular trichomes are numerous on the young leaves and over the ribbings of adult
- leaves. The tector trichomes are multicellular (two to five cells), uniserial and conical, of smooth and thin walls; the glandular trichomas are of two types: one possesses unicellular pedicel and gland composed by two to four cells arranged in two series and topped by a terminal cell, acquiring the clavi-shapped aspect, the other presents uniserial pedicel and unicellular head. The stomas, anisocytic, are more frequently on the abaxial epidermis. The mesophile is composed by a single layer of palisade parenchyma and, right below, spongy

This translation does not replace the portuguese version.

parenchyma, where occur great idioblasts full of tetrahedral crystals of calcium oxalate called bags of microcrystalline sand. The median ribbing is protruded on both faces and present bicollateral vascular beams in open arc, the intra-axillar phloem being discontinuous. Below the epidermis, on both faces of median ribbing, occur an angular collenchyma. The eustellic stem presents epidermic cells of contour approximately rectangular elongated on anticlinal direction, with stripped cuticle and some trichomes similar to the described to the leaves. Colenchymatic region little developed occurs wright below the epidermis. The cortical parenchyma is equally little developed and endoderm contains starch. The vascular beams are bicolateral and parenchyma, located internally, occur islets of elements of perimedullary plated tubes. On the cortical and medular parenchyma occur microcrystalls of calcium oxalate as well as group of fibers on the periphery of external phloem. The chalice contains multicellular grandular trichomes, uniseriate, similar to the leave's. The corolla has the intern epidermis coveres by papillae; the external epidermis has wavy anticline walls with similar trichomes to the chalice's and the leave's.

- In the microscopic exam it must not be observed fragments of leaves with raphids between the rigging (*Phytolacca americana* L.), nor present layers of cells with stains of calcium oxalate through the rigging (*Ailanthus altissima* Swingle).

DRUG IDENTIFICATION

A. Stir 3 g of pulverized drug with 30 mL of sulphuric acid 0,05 *M* for 2 minutes and filtrate. Alkanalize the filtrate with 3 mL of ammonium hydroxide and add through the filter 15 mL of purified water. Transfer the alkaline solution to the separation funnel and successively extract with three aliquots of 15 mL of chloroform. Gather the chloroformic phases and add sulphate of anhydrous sodium. Filtrate and divide the filtrate in three capsules of porcelain proceeding to the solvent evaporation. Set aside the third capsule for the execution of the test **B.** of *Drug Identification*. In one of the capsules, add 0.5 mL of steaming nitric acid and evaporate in water bath till complete dryness. Add some drops of ethanolic solution of potassium hydroxide at 3% (p/v). A purple coloring can be seen, which intensifies with the addition of 1 mL of acetone, characterizing the presence of atropine and/or hyoscyamine. On the second capsule, add a drop of *p*-dimethylamminobenzaldehyde SR2 and alightly heat it. A reddish-purple coloring can be seen (atropine and/or hyoscyamine).

B. Proceed as described in *Thin-layer chromatography* **(5.2.17.1) FB 5**, using silica gel G with thickness of 250μm as support, and mix toluene, ethyl acetate and diethylamine (7:2:1), as mobile phase. Apply, separately, to the plate, in coil form, 20 μL of each of the solutions, recently prepared, described hereinafter.

  – *Sample solution:* on the reserved capsule for this purpose, described in test **A.** of *Drug identification*, dissolve the residue with 0.25 mL of methanol.
  – *Reference solution*: dissolve 24 mg of antropine sulphate in 9 mL of methanol and 7.5 mg of escopolamine bromidate in 10 mL of ethanol. Mix 9 mL of the solution of antropine sulphate and 1 mL of solution of escopolamine bromidate.

- Develop a chromatogram in a route of 10 cm. Desiccate the plate in a temperature between 100 °C and 105 °C, for 15 minutes. Let it cool down and nebulize with potassium iodinebismuth SR2, let it dry and next nebulize with ethanolic solution of sulphuric acid at 5 % (p/v) (or aqueous solution of sodium nitrite at 5 % (p/v)), till the appearance of red or orange-red stains over a yellowish-gray background. The reference solution presents, when examined under visible light, sashs with Rf ranging from 0.30 to 0.45, refering to the hiosciammine/ atropine and sashs wit Rf ranging from 0.55 to 0.65 refering to the escopolammine. The

sashs of the chromatogram obtained with the *Sample solution* are similar, as to the position and coloring of those obtained with *Reference solution*.

PREPARATION OF MOTHER TINCTURE

- Proceed as described in *Preparations of mother tincture with plant origin* **(10.1)**. The mother tincture of *Atropa belladona* is prepared via maceration or percolation, in a way that the alcoholic strength, during and by the end of the extraction, is of 45% (v/v) according to the general technique of preparation of mother tincture.

MOTHER TINCTURE CHARACTERISTICS

- Liquid of brown coloring, of slightly aromatic odor and of slightly bitter flavor containing, at least, 0.02% of total alkaloids expressed in hiosciammine.

IDENTIFICATION

A. Acidify 5 mL of mother tincture with enough quantity of hydrochloric acid at 10% (p/v). Extract with 5 mL of ethyl ether; eliminate the ethereal phase and alkanalize the aqueous phase with enough quantity of ammonium hydroxide; extract 10 mL of ethyl ether; despise the aqueous phase; evaporate the ethereal phase in boiling water bath. With the obtained residue, add 0.5 mL of steaming nitric acid and evaporate in water bath, till dryness. Treat the residue with enough quantity of acetone and add, drop by drop, solution of potassium hydroxide at 3% (p/v) in ethanol at 96% (v/v). It develops a purple coloring.

B. Set to evaporate, in boiling water bath, 10 mL of mother tincture. Add to the obtained residue 10 mL of purified water, filtrate and extract the filtrate with 10 mL of chloroform, separate and evaporate the chloroformic extract in boiling water bath, Treat the formed residue with 10 mL of purified water previously heated and add to the formed solution, 1 mL of ammonium hydroxide. Examine under ultraviolet light (365 nm). The mix presents blue fluorescence.

C. Evaporate 1 mL of mother tincture in boiling water bath. Add to the residue some drops of hydrochloric acid at 10% (v/v). To the solution, add some drops of potassium iodinebismutate SR2. The formation of orange colored gray precipitate is observed.

D. Repeat the described operation in test **C**. of *Identification*, replacing the potassium iodinebismutate SR2 by the mercury potassium iodide SR. The formation of white precipitate is observed.

E. Proceed as described in *Thin-layer chromatography* **(5.2.17.1) FB 5**, using silica gel G, as support, and mix of 1-butanol, glacial acetic acid and water (4:1:1) as mobile phase. Apply to plate 20 μL of mother tincture. Develop a chromatogram in a route of 10 cm. Remove the plate, let it air-dry. Examine under ultraviolet light (365 nm). The chrmatogram presents, usually, two stains grayish-brown with Rf values close to 0.40 and 0.60 and a shiny blue fluorescent stain with Rf close to 0.90. A fourth stain could appear with red fluorescence and Rf close to 0.97. Next, nebulize the plate with aluminum chloride solution at 1 % (p/v) in ethanol at 96% (v/v). Examine under ultraviolet light (365 nm). Two stains can be seen with yellow fluorescence and values of Rf close to 0.40 and 0.60.

- Develop a second chromatogram, using silica gel G, as support and acetone mix, purified water and ammonium hydroxide (90:7:3) as mobile phase. Apply to the plate, 20 µL of
  - *Sample solution* and of *Standard solution*, recently prepared, described below.
  - *Sample solution*: evaporate 5 mL of mother tincture in boiling water bath. Add to the residue 2 mL of sulphuric acid 0,05 *M* and filtrate. When filtrated, add 1 mL of ammonium

hydroxide and extract with 10 mL of ethyl ether, separate the ethereal phase and desiccate it with anhydrous sodium sulphate, filtrate. Evaporate the solvent in boiling water bath. Dissolve the obtained residue with 1 mL of methanol.

– *Standard solution*: dissolve 24 mg of atropine sulphate in 9 mL of methanol in mix with solution of 7.5 mg of escopolammine bromidrate in methanol separately prepared and in which add 1 mL to the solution of atropine sulphate, at the moment of use.

- Develop a chromatogram in a route of 10 cm. Remove the plate and heat the temperature between 100 °C and 105 °C till total elimination of solvent mix. Let it cool down. Nebulize the plate, next, successively with potassium iodinebismutate SR2 and with solution of sulphuric acid 0,05 *M*. Stains of orange-red should appear over yellow background. Examine under natural light. The chromatogram obtained after the Standard solution presents stain with Rf close to 0.30 and another one with Rf close to 0.85.

PURITY TESTS

- **Title in ethanol.** The content in ethanol must be between 40% and 50% (v/v).
- **Dry residue.** The dry residue must be 1,2% (p/v) or higher.

ASSAY

- In rotavapor (or in boiling water bath), concentrate 100 g of mother tincture until the weight of the sample is reduced to 10 g. Remove the the same from flaks, if necessary with employment of some milimiters of ethanol at 70% (v/v), quantitatively transferring the same for separation funnel, followed by the addition of 5 mL of ammonium hydroxide and 2.5 mL of purified water. Successfully extract with the solvent mix formed by ethyl ether and chloroform (3:1) till the total extraction of alkaloids, ceasing the extraction when is no longer watched the reaction of the obtained extracts when the respective residues are treated with drops of hydrochloric acid 10% (v/v) and drops of potassium iodinebismutate SR2. Gather all extractions and extract them, next, with enough quantities of solution of sulphuric acid 0,3 *M*, successively. Filtrate each acid solution and gather them in another separation funnel. Alakanalize with enough quantity of ammonium hydroxide and successively extract with chloroform until the final residue has no longer a positive reaction for alkaloids with the employ of potassium iodinebismutate SR2, as the previous procedure. Wash the chloroformic solution with 10 mL of purified water; separate and concentrate the chloroformic phase till dryness in rotavapor (or in boiling water bath). Keep the flask in boiling water bath for 15 minutes. Resuspend the concentrated (residue) with enough quantity of chloroform keeping the flask in boiling water bath for 15 minutes. Dissolve again the residue qith enough quantity of chloroform. Add, to the formed solution, 20 mL of sulphuric acid, 0,01 *M* SV and eliminate the excess of chloroform by evaporation. Titrate the excess of sulphuric acid 0,01 *M* SV with sodium hydroxide 0,01 *M* SV in presence of methyl red SI. Each mL of sulphuric acid 0,01 *M* SV corresponds to 5,788 mg of total alkaloids expressed in hiosciammine.

PACKAGING AND STORAGE

- In a neutral glass, amber, tightly close container, safe from light and heat.

DERIVED FORM

- **Starting point.** Mother tincture.

This translation does not replace the portuguese version.

- **Inert ingredient.** From 1 CH to 3 CH or 1 DH to 6 DH, use the same alcoholic strength of mother tincture. For other dynamizations, follow the general rule of preparation of derived pharmaceutical forms.
- **Method.** *Hahnemannian Method* **(11.1)**, Korsakovian Method **(11.2)**, *Streaming Method* **(11.3)**.
- **Dispensation.** From 1 CH or 2 DH, following the general rule of dispensation.
- **Packaging and storage.** In a neutral glass, tightly close container, safe from light and heat.

This translation does not replace the portuguese version.

BORAX

- $Na_2B_4O_7.10H_2O$; 381,37 [*1303-96-4*]
- Contains, at least, 99.0% and, at most, 105.0% of $Na_2B_4O_7.10H_2O$.

HOMEOPATHIC SYNONYM
- Borax veneta, Natrium boracicum, Natru boras.

CHEMICAL NAME
- Sodium borate.

DESCRIPTION
- **Physical features.** White crystalline powder or colorless crystals.
- **Solubility.** Soluble in water, highly soluble in boiling water, easily soluble in glycerol, insoluble in ethanol.

IDENTIFICATION

A. Dissolve 0.2 g of the sample in water without carbon dioxide and complete the volume for 5 mL using the same solvent. Add 0.1 mL of phenolphthalein SI. It develops a red coloring. Add 5 mL of glycerol at 85% (v/v). The coloring disappears.

B. The solution prepared in the same way of test solution **A.** of *Identification* responds to the reactions of borate ion **(5.3.1.1) FB 5**.

C. The solution prepared in the same way of test solution **A.** of *Identification* responds to the reactions of sodium ion **(5.3.1.1) FB 5**.

PURITY TESTS
- **Solution aspect.** Dissolve 4 g of the sample in water without carbon dioxide and complete the volume for 100 mL using the same solvent. The obtained solution is clear **(5.2.25) FB 5** and colorless **(5.2.12) FB 5**.
- **pH (5.2.19) FB 5.** 9,0 to 9,6. Determine the solution obtained in *Solution aspect*.
- **Carbonate and bicarbonate.** On a test tube, add 5 mL of aqueous solution of the sample at 5% (p/v) and 1 mL of hydrochloric acid 3 *M*. Effervescence does not occur.
- **Ammonia (5.3.2.6) FB 5.** Dilute 6 mL of solution obtained in *Solution aspect* for 14 mL with water and proceed as described in *Limit for ammonia rehearsal*. Prepare the standard solution using a mix of 2.5 mL of the Standar solution of ammonia *(1 ppm NH3)* and 7.5 mL of water. At most 0,001% (10 ppm).
- **Arsenic (5.3.2.5) FB 5.** Use *Method I*. Use 15 mL of solution obtained in *Solution aspect* and proceed as described in *Limit for arsenic rehearsal*. At most 0.0005% (5 ppm).
- **Calcium (5.3.2.7) FB 5.** Use 15 mL of solution obtained in *Solution aspect* and proceed as described in *Limit for calcium rehearsal*. Prepare the standard solution using a mix of 6 mL of the *Standard solution of calcium (10 ppm Ca)* and 9 mL of water. At most 0,01% (100 ppm).
- **Heavy metals (5.3.2.3) FB 5.** Use 12 mL of solution obtained in *Solution aspect* and proceed as desribed in *Method 1*. Prepare the standard solution using *Diluted standard solution of lead (1 ppm Pb)*. At most 0,0025% (25 ppm).
- **Sulphates (5.3.2.2) FB 5.** Use 15 mL of solution obtained in *Solution aspect* and proceed as described in *Limit for sulphates rehearsal*. Prepare the standard solution using a mix of 3

mL of the standard solution of sulphate (10 ppm SO4) and 12 mL of water. At most 0,005% (50 ppm).

ASSAY

- Weigh, precisely, about 0.3 g of sample and dissolve in 50 mL of water. Add some drops of methyl red SI and titrate with hydrochloric acid 0,1 *M* SV. Each mL of hydrochloric acid 0,1 *M* SV correspond to 19.069 mg of $Na_2B_4O_7.10H_2O$

PACKAGING AND STORAGE

- In a neutral, amber and hermetically closed container.

DERIVED FORM

- **Starting point.** Borate of deca-hydrated sodium (Na2B4O7.10H2O).
- **Inert ingredient.** Lactose.
- **Method.** *Hahnemannian Method* **(11.1)**, Korsakovian Method **(11.2)**, *Streaming Method* **(11.3)**.
- **Dispensation.** From 6 DH trit. and 3 CH trit.
- **Packaging and storage.** In a neutral, amber and tightly closed container.

This translation does not replace the portuguese version.

BRYONIA ALBA

- *Bryonia alba* (L.) – CUCURBITACEAE

HOMEOPATHIC SYNONYM
- Bryonia, White brionia.

EMPLOYED PART
- Dry root.

PLANT DESCRIPTION
- *Bryonia alba* L. is a crawling or climbing herbaceous plant, perennial, monoecious, with root ranging from fusiform to napiform, branchy measuring approximately 60 cm of length by 5 cm to 10 cm of diameter, codiform leaves with five rough lobes, of bright green coloring. The stem is canaliculated rough, with tendrils of greenish coloring. The flowers are small, yellowish-white, monoecious with numerous transversal stripes, disposed in racemes; the male flowers, with long pedicels, are smaller than the female's. The fruits are dark berries with approximately 6 mm of diameter. The plant presents unpleasant odor, nauseous, of, initially acre, bitter flavor.

DRUG DESCRIPTION
- As well as the napiform roots, the fusiform roots present wrinkled external surface, yellow or grayish, striped, marked by deep and transversal grooves. They measure approximately 60 cm of length by 5 cm to 10 cm of diameter. Sectioned, present grayish suber and yellowish cortex with concentric stripes separated by widely large slumps. The cortical cylinder is narrow and the region of lenho is well developed. The odor is null, the flavor is acre, becoming bitter, unpleasant. When sectioned, right after the collection, the root presents whitish latex.

MICROSCOPIC DESCRIPTION
- Presents numerous concentric circles of collateral libero-woody beams; on cortical parenchyma and on liber are watched lactiferes cells that are stained when treated by sulphuric acid. Its sections present granules of starch of roun and long shape. The cortical parenchyma presents polygonal cells containing some sclerids and numerous yellowish lactiferes vases. Does not present inclusions of calcium oxalate.

PREPARATION OF MOTHER TINCTURE
- Proceed as described in *Preparations of mother tincture with plant origin* **(10.1)**. The mother tincture of *Bryonia alba* L is prepared via maceration or percolation, in a way that the ethanolic strength, during and by the end of the extraction, is of 45% (v/v) according to the general technique of preparation of mother tincture.

MOTHER TINCTURE CHARACTERISTICS
- Liquid of light-yellow coloring, of nauseous, unpleasant odor and of bitter flavor.

IDENTIFICATION
A. With 1 mL of mother tincture, add 1 mL of alkaline cupric tartrate SR. Heat till boiling. It is observed the reduction of the reagent, that goes from initially yellow to posterior formation of yellow precipitate.

This translation does not replace the portuguese version.

B. With 1 mL of mother tincture, add 1 mL of Tollens reagent and heat till boiling. It is observed the reduction of the reagent with the formation of black precipitate.

C. With 1 mL of mother tincture, add 0.5 mL of the mix prepared at the moment of use and formed by equal parts of solution of ferric chloride at 1% (p/v) and solution of potassium ferrocyanide at 1% (p/v). It develops an intense blue coloring.

D. With 1 mL of mother tincture, add some drops of ninhydrin solution at 1% (p/v) in ethanol at 96% (v/v), put to heating in boiling water bath for 2 minutes. It develops a purple coloring.

E. With 5 mL of mother tincture, add 5 mL of ethyl ether, stir vigorously. Separate the ethereal phase, add 1 mL of the solution of *p*-dimethilamminobenzaldehide at 1% (p/v) in sulphuric acid. It can be seen the separation of two phases, the ethereal phase acquires a green coloring, and the aqueous, a pink coloring.

F. Proceed as described in *Thin-layer chromatography* **(5.2.17.1) FB 5**, using silica gel G, as support, and mix of 1-butanol, glacial acetic acid and water (4:1:1) as mobile phase. Apply to plate 20 μL of mother tincture. Develop a chromatogram in a route of 10 cm. Remove the plate, let it air-dry. Examine under ultraviolet light (365 nm). The chromatogram presents, usually, a stain with yellow fluorescence with Rf close to 0,45 and two blue fluorescent stains with Rf values close to, respectively, 0.55 and 0.60. On a second stage, nebulize the plate with solution of aniline phthalate, heating it for 10 minutes at 105 °C, Examine under natural light. The chromatogram presents a brown stain, slightly intense, with Rf close to 0.10 and two other, also, of dark brown coloring, with values of Rf close to 0.25 and 0.35.

PURITY TESTS

- **Title in ethanol.** Must be between 40% and 50% (v/v).
- **Dry residue.** Must be 1,25% (p/v) or higher.

PACKAGING AND STORAGE

- In a neutral glass, amber, tightly close container, safe from light and heat.

DERIVED FORM

- **Starting point.** Mother tincture.
- **Inert ingredient.** From 1 CH to 3 CH or 1 DH to 6 DH, use the same strength of mother tincture. For other dynamizations, follow the general rule of preparation of derived pharmaceutical forms.
- **Method.** *Hahnemannian Method* **(11.1)**, Korsakovian Method **(11.2)**, *Streaming Method* **(11.3)**.
- **Dispensation.** From 1 CH or 2 DH, following the general rule of dispensation.
- **Packaging and storage.** In a neutral glass, tightly close container, safe from light and heat.

This translation does not replace the portuguese version.

CALCAREA CARBONICA

- The drug is constituted by the intermediate part of the oyster shell (*Ostrae edulis* L.), from which is obtained, after cleaning for removal of adherences to the shell, it is dried till the constant weight and transformed in powder.

HOMEOPATHIC SYNONYM
- Calcarea ostreica, Calcarea carbonica Hahnemanni, Calcarea ostrearum, Calcii carbonas ostrearum.

CHEMICAL NAME
- Salt of calcium of carbonic acid.

DESCRIPTION
- **Physical features.** The powder obtained from the oyster shell is white, microcrystalline, odorless, tasteless, constituted by approximately 85% of calcium carbonate. Besides the calcium, under the form of carbonate, the oyster shell presents also traits of chloride, phosphate and magnesium.
- **Solubility.** Is practically insoluble in water and ethanol, is soluble in acids, with which reacts detaching carbon dioxide.
- **Incompatibilities.** Acids, acid salts.

IDENTIFICATION

A. The calcium carbonate of the oyster shell responds to the characteristic reactions of calcium and carbonate **(5.3.1.1) FB 5**.

B. Proceed as described in *Thin-layer chromatography* **(5.2.17.1) FB 5**, using thin layer of microcrystalline cellulose, as support, and mix of methanol, acetic acid and water (8:1:1) as mobile phase. Apply, separately, leaving a minimal space of 1.5 cm between the applications, 3 µL of *Sample solution* and 1 µLof *Standard solution(1)* and of *Standard solution (2)*, recently prepared, described below.
  - *Sample solution*: submit 0.1 g of the sample to a previous treatment with acid solution formed by 5 mL of purified water and 0.2 mL of nitric acid at 10% (v/v).
  - *Standard solution (1)*: solution of calcium chloride at 0.1% (p/v).
  - *Standard solution (2)*: solution of magnesium sulphate at 1% (p/v).
- Develop a chromatogram in a route of 10 cm. Remove the plate, let it air-dry. Nebulize the plate with solution of alizarin 0,1% (p/v), submitting it, next, to vapors of ammonium hydroxide. It appears, in chromatogram, referring to the solution in analysis, two stains, respectively of intense purple coloring and Rf of 0.79, correspondent to that obtained with *Standard solution (1)* and other, light-purple, with Rf of 0.90 correspondent to that obtained in *Standard solution (2)*.

PURITY TESTS
- **Loss by desiccation (5.2.9) FB 5.** Determine in 1g of the sample, finely divided, dried in stove at temperature between 100 °C and 105 °C, till constant weight, should not loose more than 3% (p/p) in relation to the initial weight.

This translation does not replace the portuguese version.

ASSAY

- Weigh 200 mg of the finely divided drug and previously dried at 200 °C for 4 hours. Transfer it to a beaker of 250 mL. Humidify the solid with some milimiters of purified water. Add, drop by drop, hydrochloric acid 3 *M* in enough quantity fot complete dissolution of the sample. Add 100 mL of purified water, 15 mL of sodium hydroxide SR and 300 mg of hydroxinaftol blue. Titrate the mix with disodium edetate 0,05 *M* SV till the solution acquires blue coloring. Each mL of disodium edetate 0,05 *M* SV corresponds to 5,004 mg of calcium carbonate.

PACKAGING AND STORAGE

- In a neutral glass, amber, hermetically closed container, safe from light and heat.

DERIVED FORM

- **Starting point.** Carbonic calcarea.
- **Inert ingredient.** Lactose on the three fist centesimals and six first decimals, ethanol in various concentrations for the following.
- **Method.** *Hahnemannian Method* **(11.1)**, Korsakovian Method **(11.2)**, *Streaming Method* **(11.3)**.
- **Dispensation.** From 1 DH trit. or 1 CH trit.
- **Packaging and storage.** In a neutral, amber and tightly closed container.

This translation does not replace the portuguese version.

CALCAREA MURIATICA

- $CaCl_2$; 110,98 [*10043-52-4*]
- $CaCl_2.2H_2O$; 146,98 [*74033-92-4*]
- Contains, at least, 97.0% and, at most, 103.0% of $CaCl_2.2H_2O$.

HOMEOPATHIC SYNONYM
- Calcium hydrochloricum, Calcii chloridrum, Calcium chloratum, Chloridum calcium, Calcii chlorurum.

CHEMICAL NAME
- Calcium chloride.

DESCRIPTION
- **Physical features.** White crystalline powder, hygroscopic.
- **Solubility.** Easily soluble in water, soluble in ethanol.

IDENTIFICATION
A. Dissolve 1 g of the sample in water without carbon dioxide and complete to 10 mL with the same solvent. The obtained solution responds to the reactions of calcium ion **(5.3.1.1) FB 5**.
B. Dissolve 1 g of the sample in water without carbon dioxide and complete to 10 mL with the same solvent. The obtained solution responds to the reactions of chloride ion **(5.3.1.1) FB 5**.

PURITY TESTS
- **Solution aspect.** Dissolve 10 g of the sample in water without carbon dioxide and complete to 100 mL with the same solvent. The obtained solution is clear **(5.2.25) FB 5** and is no more stained than the mix of 5 mL of the *Standard solution of SC color F* and 95 mL of hydrochloric acid at 1% (p/v) **(5.2.12) FB 5**.
- **Acidity or alkalinity.** With 10 mL of the solution obtained in *Solution aspect*, recently prepared, add 0.1 mL of phenolphtalein SI. If the solution acquires a pink coloring, it should become colorless by the addition of, at most, 0.2 mL of hydrochloric acid 0.01 *M*. If no color should appear, it must become pink bu the addition of, at most, 0.2 mL of sodium hydroxide 0.01*M*.
- **pH (5.2.19) FB 5.** 4,5 to 9,2. Set in aqueous solution at 5% (p/v).
- **Barium.** With 10 mL of the solution obtained in *Solution aspect*, add 1 mL of calcium sulphate SR. After 15 minutes, any observed opalescence is no more intense than the mix of 10 mL of the solution obtained in *Solution aspect* and 1 mL of water.
- **Iron, aluminum and phosphate.** Dissolve 1 g of the sample in 20 mL of water. Add two drops of hydrochloric acid 3 *M* and a drop of phenolphtalein SI. Add, drop by drop, ammonium chloride-ammonium hydroxide SR, till light pink coloring and add two drops in excess. Heat till boiling. Doesn't occur turbidity nor precipitation.
- **Magnesium and alkaline metals.** Mix 20 mL of the solution obtained in *Solution aspect* and 80 mL of water. Add 2 g of the sample in 2 mL of ammonia SR. Heat till boiling and add hot solution of 5 g of ammonium oxalate in 75 mL of water. Let it rest for 4 hours, complete for 200 mL with water and filtrate. With 100 mL of the filtrate, add 0.5 mL of sulphuric acid. Evaporate to dryness in water bath and incinerate at 600 °C till constant weight. The residue weight must not be higher than 5 mg. At most 0,5%

This translation does not replace the portuguese version.

- **Aluminum.** With 10 mL of the solution obtained in Solution aspect, add 2 mL of ammonium chloride SR, 1 mL of ammonia SR and boil the solution. Doesn't occur turbidity nor precipitation.
- **Arsenic (5.3.2.5) FB 5.** Use *Method I*. Set in 1g of sample. At most 0.0003% (3 ppm).
- **Iron (5.3.2.4) FB 5.** Use *Method I*. Use 10 mL of the solution obtained in *Solution aspect*. Use standard solution of iron (1 ppm Fe). At most 0,001% (10 ppm).
- **Sulphates (5.3.2.2) FB 5.** Set in 4 g of sample. At most 0,03% (300 ppm).
- **Heavy metals (5.3.2.3) FB 5.** Use *Method I*. Use 10 mL of the solution obtained in *Solution aspect*. Prepare the standard solution using standard solution of lead (2 ppm Pb). At most 0,002% (20 ppm).

ASSAY
- Weigh, exactly, close to 0.28 g of sample, dissolve in 100 mL of water ans proceed as described in Complexometric titration **(5.3.3.4) FB 5** for determination of *Calcium*, using 4 mL of sodium hydroxide 2 *M* and disodium edetate 0,1 *M* SV, as titrant. Each mL of disodium edetate 0.1 *M* SV corresponds to 14,702 mg of $CaCl_2.2H_2O$.

PACKAGING AND STORAGE
- In tightly closed containers.

DERIVED FORM
- **Starting point.** Chloride of anhydrous calcium ($CaCl_2$).
- **Inert ingredient.** Hydroethanolic solution in different scales.
- **Method.** *Hahnemannian Method* **(11.1)**, Korsakovian Method **(11.2)**, *Streaming Method* **(11.3)**
- **Dispensation.** From 3 DH or 2 CH.
- **Packaging and storage.** In a neutral, amber and tightly closed container.

This translation does not replace the portuguese version.

CALCAREA PHOSPHORICA

- $Ca_3(PO_4)_2$; 310,18 [*7758-87-4*]
- Contains, at least, 85% of $Ca_3(PO_4)_2$.

HOMEOPATHIC SYNONYM
- Calcium phosphoricum, Calcarea phosphorata, Calcium phosphas.

CHEMICAL NAME
- Orto-phosphate of calcium, tricalcium phosphate, phosphate of tribasic calcium.

DESCRIPTION
- **Physical features.** White powder, shapeless or microcrystalline, stable to air. Odorless and tasteless.
- **Solubility.** Practically insoluble in water, slightly decomposing itself in hot water. Easily soluble in diluted hydrochloric acid and nitric acid at 10% (v/v). Insoluble in ethanol.
- **Relative density (5.2.5) FB 5.** 3,14 g/mL to 20 °C.

IDENTIFICATION

A. A small quantity, dampened with hydrochloric acid, carried in platinum strap to the non-illuminating zone of Bunsen burner flame, develops a orange-red coloring to itself.

B. Dissolve 0.1 g of calcium phosphate in 5 mL of solution of nitric acid at 10% (v/v). Add five drops of solution of silver nitrate at 1% (p/v). It can be seen the formation of yellow precipitate, soluble in excess of nitric acid and also in excess of ammonium hydroxide.

C. Dissolve 0.1 g of calcium phosphate in 5 mL of solution of hydrochloric acid at 10% (v/v). Add five drops of solution of oxalic acid at 1% (p/v). It can be seen the formation of white crystalline preciputate, soluble in mineral acids,

PURITY TESTS
- **Arsenic (5.3.2.5) FB 5.** Proceed as described in *Limit for arsenic rehearsal*. At most 0,0005% (5 ppm).
- **Barium.** Add 0.5 g of the sample in 10 mL of purified water and add 1 mL of nitric acid. The solution should remain clear after the addition of 1 mL of calcium sulphate SR1.
- **Carbonate.** The addition of hydrochloric acid 3 *M* to the sample should not produce effervescence.
- **Chloride (5.3.2.1) FB 5.** Add 0.14 g of the sample in 10 mL of purified water and add 1 mL of nitric acid. Stir till dissolution, dilute for 40 mL with purified water, transfer for test tube and proceed as described in *Limit for chlorides rehearsal*. At most 0,25% (2500 ppm).
- **Iron (5.3.2.4) FB 5.** Use the *Method 1*. Add 0.2 g of the sample with 10 mL of purified water and add 1 mL of hydrochloric acid and 1 g of citric acid, previously pulverized. After complete dissolution, alkalinize with ammonium hydroxide. Dilute for 40 mL with purified water, transfer for test tube and proceed as described in *Limit for iron rehearsal*. At most 0,05% (500 ppm).
- **Heavy metals (5.3.2.3) FB 5.** Use the *Method 1*. Add 0.333 g of the sample in 2.3 mL of hydrochloric acid *M* heat in water bath for 5 minutes and dilute with purified water for 35 mL. Filtrate, transfer for the test tube and proceed as described in *Limit for heavy metals rehearsal*. At most 0,003% (30 ppm).

This translation does not replace the portuguese version.

- **Sulphates (5.3.2.2) FB 5.** Add 0.5 g of the sample in 10 mL of purified water, add 1 mL of hydrochloric acid and stir till dissolution. Dilute for 40 mL with purified water, transfer for Nessler tube and proceed as described in *Limit for sulphates rehearsal*. At most 0,24% (2400 ppm).

ASSAY

- Weigh 0.15 g of calcium phosphate, with precision of 1 mg, dissolve in a mix of 5 mL of hydrochloric acid and 3 mL of purified water, contained in a beaker of 250 mL with magnetic stirring bar and add, slowly, 125 mL of purified water. In case of difficulty of dissolution, slightly heat the mix. With constant stirring, add the reagents in the following order: 0.5 mL of triethanolammina, 0.3 g of hidroxinaphtol blue indicator and, with the assistance of a burette of 50 mL, approximately 23 mL of disodium edetate 0,05 *M* SV. Add solution of sodium hydroxide at 45% (p/v) till the initial red coloring turns into light blue. Continue the addition, drop by drop, till coloring changes to violet and, than, add the excess of the same reagent (0.5 mL). The pH of the mix should be between 12.3 and 12.5. Continue the titration, drop by drop, with disodium edetate 0,05 *M* SV till the appearance of light blue final point that persists for, at most, 1 minute. Each mL of disodium edetate 0,05 *M* SV is equivalent of 0.200 g of Ca or 0.517 g of $Ca_3(PO_4)_2$.

PACKAGING AND STORAGE

- In a neutral, amber and tightly closed glass container.

DERIVED FORM

- **Starting point.** Tricalcium phosphate $Ca_3(PO_4)_2$
- **Inert ingredient.** Use lactose till 3 CH or 6 DH and for the rest, follow the general rule of preparation of derived pharmaceutical forms.
- **Method.** *Hahnemannian Method* **(11.1)**, Korsakovian Method **(11.2)**, *Streaming Method* **(11.3)**.
- **Dispensation.** From 1 CH or 1 DH, following the general rule of dispensation.
- **Packaging and storage.** In a neutral, amber and tightly closed glass container.

This translation does not replace the portuguese version.

CALCAREA SULPHURICA

- $CaSO_4.2H_2O$; 172,17 [*10101-41-4*]
- Contains, at least, 98.0% and at most, 101.0 % of CaSO4, relating to the dry substance.

HOMEOPATHIC SYNONYM
- Calcium sulphuricum.

CHEMICAL NAME
- Sulphate of di-hydrated calcium.

DESCRIPTION
- **Physical features.** Thin, white or almost white powder.
- **Solubility.** Very little soluble in water, practically insoluble in ethanol.

IDENTIFICATION
A. Responds to the reactions of sulphate ion **(5.3.1.1) FB 5**.
B. Responds to the reactions of calcium ion **(5.3.1.1) FB 5**.

PURITY TESTS
- **Acidity or alkalinity.** Stir for 5 minutes 1.5 g of the sample with 15 mL of water without carbon dioxide. Let it rest for 5 minutes and filtrate. With 10 mL of filtrate, add 0.1 mL of phenolphtalein Si and 0.25 mL of sodium hydroxide 0,01 *M*. A red coloring is developed. Add 0.30 mL of hydrochloric acid 0.01 *M*. The solution becomes colorless. Add 0.2 mL of methyl red SI. A reddish-orange coloring is developed.
- **Arsenic.** Dissolve, heating at 50 °C for 5 minutes, 1 g of the sample in 50 mL of hydrochloric acid at10% (v/v). Cool down and proceed as described in *Visual Method*, described below, using 5 mL of this solution. At most 0,001% (10 ppm).
  - *Visual method*: in a test tube containing 4 mL of hydrochloric acid and approximately 5 mg of potassium iodate, insert the prescribed quantity of the sample. Add 3 mL of hypophosphoric reagent. Heat the mix in water bath for 15 minutes, with stirring. Prepare the standard with the same conditions, using 0.5 mL of standard solution of arsenic (10 ppm As). After heating in water bath, the eventual coloring of the sample solution should not be more intense than the standard's.
- **Iron (5.3.2.4) FB 5.** Use *Method I*. Dissolve 0.1 g of the sample in 8 mL of hydrochloric acid 3 *M*. Use 1 mL of *Standard solution of iron (10 ppm Fe)*. At most 0,01% (100 ppm).
- **Heavy metals (5.3.2.3) FB 5.** Use the *Method 1*. Mix 2 g of the sample with 20 mL of water, add 25 mL of hydrochloric acid 3 *M*, and heat till boiling for the total dissolution of the sample. Cool down and add ammonium hydroxide till pH 7.0. Filtrate and reduce the filtrate volume to 25 mL and filtrate again, if necessary. At most 0,001% (10 ppm).
- **Loss by desiccation (5.2.10) FB 5.** Determine in minimal temperature of 250 °C, till constant weight. For the di-hydrated form, the loss is between 19.0% and 23.0 %. For the anhydrous form, at most 1.5%.

ASSAY
- Weigh, precisely, about 0.15 g of sample and dissolve in 120 mL of water. Proceed as described in *Complexometric titrations* **(5.3.3.4) FB 5** to determination of *Calcium*, using

disodium edetate 0,1 *M* SV. Each mL of disodium acid 0,1 M SV corresponds to 13,614 mg of $CaSO_4$.

PACKAGING AND STORAGE
- In tightly closed containers.

DERIVED FORM
- **Starting point.** Sulphate of di-hydrated calcium ($CaSO_4.2H_2O$).
- **Inert ingredient.** Use lactose till 3 CH or 6 DH and for the rest, follow the general rule of preparation of derived pharmaceutical forms.
- **Method.** *Hahnemannian Method* **(11.1)**, Korsakovian Method **(11.2)**, *Streaming Method* **(11.3)**.
- **Dispensation.** From 1 CH or 1 DH, following the general rule of dispensation.
- **Packaging and storage.** In a neutral, amber and tightly closed glass container.

This translation does not replace the portuguese version.

CALENDULA OFFICINALIS

- *Calendula officinalis* (L.) – COMPOSITAE (ASTERACAE)

HOMEOPATHIC SYNONYM
- Calendula, Caltha officinallis, Caltha vulgaris.

EMPLOYED PART
- Blooming summits.

PLANT DESCRIPTION
- Annual herbaceous plat with fibrous root. Presents scattered stems of 15 cm to 45 cm high with numerous striped, leafy, fleshy and pubescent branches. Oblong, sharp, little fleshy, large and codiform leaves at the base; the superior leaves are lanceolate, with complete border, frequently hispida with short hair. Big blooming luminaries, terminals, solitaries in each branch, yellow or orange.

DRUG DESCRIPTION
- The floral chapters measure 3 cm to 5 cm of radius. The casing is espheric, the petals are insertes over two rings. The flowers are striped of yellow or orange-yellow coloring; those of the periphery are petals of 2.5 cm of length ended by three dents; those of the center are of dark yellow or brownish coloring, as variety.

PREPARATION OF MOTHER TINCTURE
- Proceed as described in *Preparations of mother tincture with plant origin* **(10.1)**. The mother tincture of *Calendula officinalis L.* is prepared via maceration or percolation, in a way that the alcoholic strength, during and by the end of the extraction, is of 65% (v/v) according to the general technique of preparation of mother tincture.

MOTHER TINCTURE CHARACTERISTICS
- Liquid of yellowish-brown coloring, with unpleasant odor.

IDENTIFICATION

A. **A.** With 1 mL of mother tincture, add 10 mL of purified water in a test tube. Stir vigorously. It is observed a great quantity of foam that persists for approximately one hour.

B. With 1 mL of mother tincture, add 5 mL of ethyl ether and a little of activated carbon. Stir and filtrate. Evaporate 2 mL of the filtrate in water bath till it dries. Add to residue 1 mL of a mix of equal parts of acetic anhydride and chloroform. Add 1 mL of sulphuric acid. It is developed a red coloring that becomes dark brown.

C. With 1 mL of mother tincture, add 1 mL of alkaline cupric tartrate SR and heat. It is obeserved a orange-red precipitate.

D. Proceed as described in *Thin-layer chromatography* **(5.2.17.1) FB 5**, using silica gel G, as support, and mix of anhydrous formic acid, glacial acetic acid, water and ethyl acetate (11:11:27:100) as mobile phase. Apply, separately to the plate, 30 µL of mother tincture and 10 µL of *Standard solution*, recently prepared, described below.
  – *Standard solution*: dissolve 10 mg of rutin and 5 mg of chlorogenic acid in methanol and complete the volume for 10 mL with the same solvent.

This translation does not replace the portuguese version.

- Develop a chromatogram in a route of 10 cm. Remove the plate, let it air-dry. Examine under ultraviolet light (365 nm). The chromatogram obtained with the *Standard solution* presents a brown fluorescent stain with Rf close to 0.35 (corresponding to the rutin) and one blue fluorescent stain with Rf close to 0.55 (corresponding to the chlorogenic acid). The chromatogram obatined with the mother tincture usually presents a fluorescent stain with Rf close to 0.25, a blue fluorescent stain with Rf close to 0.30, a brown fluorescent stain with Rf close to 0.35 (rutin), twou blue fluorescent stains with Rf values cole to 0.55 (chlorogenic acid) and 0.95, and a red stain close to the solvent line. Next chromatogram with solution of aminoethanol difenilborate at 1% (p/v). Examine under ultraviolet light (365 nm). The chromatogram obtained with the *Standard solution* presents an orange fluorescent stain with Rf close to 0.35 (rutin) and one green stain with Rf close to 0.55 (chlorogenic acid). The chromatogram obtained with the mother tincture presents green fluorescent stain with Rf close to 0.30, an orange fluorescent stain with Rf close to 0.35 (rutin), a green fluorescent stain with Rf close to 0.55 (chlorogenic acid), a light orange fluorescent stain with Rf close to 0.60, and a green fluorescent stain with Rf close to 0.90. The chromatogram obtained with the mother tincture also presents yellow fluorescent stain, corresponding to the gluocarmnósido-isoramnetina situates under the orange fluorescent stain of the rutin, and other stain of yellow fluorescence correspondind to the narcisina situated between the stains that correspond to the rutin and to the chlorogenic acid.

PURITY TESTS
- **Title in ethanol.** Must be between 50% and 60% (v/v).
- **Dry residue.** Must be 0,75% (p/v) or higher.

PACKAGING AND STORAGE
- In a neutral glass, amber, tightly close container, safe from light and heat.

DERIVED FORM
- **Starting point.** Mother tincture.
- **Inert ingredient.** From 1 CH to 3 CH or 1 DH to 6 DH, use the same alcoholic strength of mother tincture. For other dynamizations, follow the general rule of preparation of derived pharmaceutical forms.
- **Method.** *Hahnemannian Method* **(11.1)**, Korsakovian Method **(11.2)**, *Streaming Method* **(11.3)**.
- **Dispensation.** From mother tincture, following the general rule of dispensation.
- **Packaging and storage.** In a neutral glass, amber, tightly close container, safe from light and heat.

This translation does not replace the portuguese version.

CARDUUS MARIANUS

- *Silybum marianum* (L.) Gaertn – COMPOSITAE ASTERACEAE

HOMEOPATHIC SYNONYM
- Carduus, Cnicus marianus, Silybum marianum.

EMPLOYED PART
- Dry fruits.

PLANT DESCRIPTION
- *Silybum marianum* (L.) Gaertn is a herbaceous plant, with approximately 1.3 m to 1.5 m high, deciduous, biannual, with axomorfa root, with glabra in its most part, solid, branched stem. The leaves are amplixistems, those on the base are pinnatifid, of dark green and shiny coloring, with 30 cm to 75 cm of length and 15 cm to 30 cm of width, wavy. All leaves present on its edges numerous yellow thorns. Median ribbing is large. Limbo of marmorised coloring, with white stains next to the ribbing and irregularly distributed. The inflorescence is constituted by isolated, globular chapters, with 3 cm to 4.5 cm of diameter, located at the branches apex. The flowers, bisexuals, present tube shaped corolla with five long lobes of violet-red coloring. The fruits are achenes, ellipsoid-compressed.

DRUG DESCRIPTION
- The fruits of *Silybum marianum* (L.) Gaertn are achenes with 4 mm to 6 mm of length and 3.0 mm to 3.5 mm of width, ellipsoid-compresses, smooth, of dark brown coloring and of slightly marmorised aspect, with the rest of floral crown that forms a small ring of light yellow coloring. Integument reduced to a thin yellow-brown skin, translucent. The fruits are odorless and tasteless.

PREPARATION OF MOTHER TINCTURE
- Proceed as described in *Preparations of mother tincture with plant origin* **(10.1)**. The mother tincture of *Carduus marianu* is prepared via maceration or percolation, in a way that the alcoholic strength, during and by the end of the extraction, is of 65% (v/v) according to the general technique of preparation of mother tincture.

MOTHER TINCTURE CHARACTERISTICS
- Liquid of yellow coloring, herbaceous odor and practically tasteless.

IDENTIFICATION
A. With 1 mL of mother tincture, add 1 mL of hydrochloric acid at 10% (v/v) and fragments of metallic zinc or metallic magnesium. It develops a red coloring.
B. With 1 mL of mother tincture, add five drops of solution of potassium hydroxide at 30% (p/v). Heat it. There is a detachment of vapors with trimethilammina odor.
C. In a test tube, add 2 mL of mother tincture. Add 1 mL of alkaline cupric citrate SR. Heat in boiling water bath for approximately 1 minute. The formation of yellow precipitate is observed.
D. In a test tube, add 1 mL of mother tincture. Add, subsequently, 10 drops of formed reagent, at the time of use, by equal parts of ferric chloride at 1% (p/v) and potassium ferricyanide at 1% (p/v). Dark blue coloring is developed.

This translation does not replace the portuguese version.

E. In a test tube, add 2 mL of mother tincture. Add 1 mL of Tollens reagent. It is observed a developing of dark brown coloring with formation of dark brown precipitate. Next, heat in boiling water bath for approximately 1 minute. It is observed the brown coloring changing to a black coloring with the increment of the precipitate.

F. In a test tube, add 1 mL of mother tincture. Add 10 drops of ninhydrin solution at 1% (p/v). Next, heat in boiling water bath for approximately 1 minute. It develops an intense blue-violet coloring.

G. Proceed as described in *Thin-layer chromatography* **(5.2.17.1) FB 5**, using silica gel G, as support, and mix of toluene, ethyl acetate and anhydrous formic acid (20:20:10) as mobile phase. Apply to plate 20 μL of mother tincture. Develop a chromatogram in a route of 10 cm. Remove the plate, let it air-dry. Examine under ultraviolet light (365 nm). The chromatogram presents, usually, a stain of blue fluorescence with Rf close to 0.20, another one, brown, with Rf close to 0.70 and a third one, with blueish fluorescence, with Rf close to 0.80. Next, nebulize the plate with aluminum chloride solution at 1% (p/v). Examine under ultraviolet light (365 nm). The chromatogram presents two stains with yellowish-green fluorescence and Rf values close to 0.65 to 0.70 and a third, with greenish-blue fluorescence and with Rf value close to 0.80.

PURITY TESTS

- **Title in ethanol.** Must be between 60% and 70% (v/v).
- **Dry residue.** Must be 0,40% (p/v) or higher.

PACKAGING AND STORAGE

- In a neutral glass, amber, tightly close container, safe from light and heat.

DERIVED FORM

- **Starting point.** Mother tincture.
- **Inert ingredient.** From 1 CH to 3 CH or 1 DH to 6 DH, use the same alcoholic strength of mother tincture. For other dynamizations, follow the general rule of preparation of derived pharmaceutical forms.
- **Method.** *Hahnemannian Method* **(11.1)**, Korsakovian Method **(11.2)**, *Streaming Method* **(11.3)**.
- **Dispensation.** From mother tincture, following the general rule of dispensation.
- **Packaging and storage.** In a neutral glass, amber, tightly close container, safe from light and heat.

This translation does not replace the portuguese version.

CHAMOMILLA

- *Matricaria chamomilla* (L.) – COMPOSITAE (ASTERACEAE)

HOMEOPATHIC SYNONYM
- Chamomilla vulgaris, Anthemis vulgaris.

PART USED
- Whole blooming plant.

PLANT DESCRIPTION
- *Matricaria chamomilla* L. is an annual herbaceous plant with big, woody roots. And upright, solid, smooth, shiny and very striated stem of 30 to 60 cm with long and lean branches. They are numerous, alternating and embracing the stem; the upper ones are simple and the other ones and bipinnate or tripinnate with long, angular and pointy leaflets.
- It displays long conic sections, with ligulated marginal female flowers, in numbers from ten to twenty and, in general, 6 mm to 9 mm long; the ligule is white, elliptical, oblong-shaped, trident-shaped in the vertex and covered by four veins. The internal flowers or disc flowers are hermaphrodite, numerous, in average with the yellow, tube-shaped, five-dent-shaped corolla of 2 mm, that shows five stamen with united anthers; from the tube, the tip of the stylus is highlighted with two curved stigmas. All flowers do not display crop. The receptacle is nude, conic, measuring up to 6 mm long, destitute of pallets and hollow on the inside. The casing is concave and made up of three rows of bracts, whose quantity varies from twenty to thirty. The bracts are lanceolate, obtuse, yellowish, largely scarious, whole in the vertex and measuring up to 2,5 mm long.
- The receptacle, involved by an epidermis, is made up of a fundamental parenchyma that surrounds the large secreting channels of schizogenic origin, that have small oily drops of the color yellow. Delicate vascular bundles may also be observed in this region. The casing's bracts has a vascular bundle, followed, in both sides, by two sclerous blades that reach the bract's margin and have short canicular fibers; the external surface shows some glandular piles of the compound type. They consist of three to four pavements of cells divided in two series and with their cuticle involving the gland like a bag. The upper epidermis of the ligulated flowers is papillous, as well as the ends of the tube-shaped flowers' dents; both flowers have, externally, glandular piles of the compound type.
- The ovary displays numerous glands of the same kind, and shows, in the epidermal layer, series of small, polyhedral, mucilaginous cells, in the shape of a rope ladder, and chrystalliferous cells, with small calcium oxalate drusen. The pollen grains are triangular-rounded, with thorny exine, containing three germination pores and a 25 μm diameter, in average.

DRUG DESCRIPTION
- The drug displays the characteristics previously detailed in *Plant description*.

MOTHER TINCTURE PREPARATION
- Proceed according to what was described in the *Preparation of the plant origin mother tincture* (**10.1**). The mother tincture of *Chamomilla* is prepared by maceration or percolation, so that the alcohol content, both throughout and at the end of the extraction, is 45% (v/v), according to the general technique of mother tincture preparation.

This translation does not replace the portuguese version.

MOTHER TINCTURE CHARACTERISTICS

- Intense yellow liquid with aromatic odor and bitter taste.

IDENTIFICATION

A. To 1mL of the mother tincture, add 15 mL of purified water. Make the solution alkaline with the sufficient amount of ammonium hydroxide at 10% (v/v). Examine under ultraviolet light (365 nm). Observe a blue fluorescence.

B. Stir up 5 mL of the mother tincture with 10 mL of petroleum ether. Separate the ethereal phase and reduce the volume to 1/3, carefully, in water bath. Add four drops of hydrochloric acid at 10% (v/v). It will develop at green color.

C. Add 1mL of the mother tincture, 1 mL of the alkaline cupric tartrate SR. Boil it. Observe a brick-red precipitate.

D. Proceed according to what was described in *Thin layer chromatography* **(5.2.17.1) FB 5**, using silica gel as a support, and a mixture of 1-butanol, glacial acetic acid and purified water (4:1:1) as the mobile phase. Apply 20 μL of the mother tincture to the plate. Develop the chromatogram for a 10 cm path. Remove the plate and let it air dry. Examine under ultraviolet light (365 nm). The chromatogram usually shows a fluorescent violet stain with Rf close to 0,80 and a red stain with Rf close to 0,95. It may also display a fluorescent light blue stain between the two previous stains.

PURITY TESTS

- **Ethanol title.** Must be between 40% and 50% (v/v).
- **Dry residue.** Must be equal or superior to 1,2% (p/v).

PACKAGING AND STORAGE

- In a neutral and amber glass recipient, very well closed and away from the light and heat.

DERIVED FORMS

- **Starting point.** Mother tincture
- **Inert ingredient.** From 1 CH until 3 CH or 1 DH until 6 DH, using the same alcoholic content of the mother tincture. For the other dynamizing procedures, follow the general separation rule of derived pharmaceutical forms.
- **Method.** *Hahnemannian method* **(11.1)**, *Korsakovian method* **(11.2)**, *Continuous flow method* **(11.3)**.
- **Dispensation.** From the mother tincture, following the general dispensation rule.
- **Packaging and storage.** In a neutral and amber glass recipient, very well closed and away from the light and heat.

This translation does not replace the portuguese version.

CHELIDONIUM

- *Chelidonium majus* (L.) – PAPAVERACEAE

HOMEOPATHIC SYNONYM
- Chelidonium majus, Celidônia, Celidonia maior, Quelidônio.

PART USED
- Whole flowered plant, including the root.

PLANT DESCRIPTION
- *Chelidonium majus* L. is a herbaceous perennial and deciduous plant, with spindle-shaped root, brown-red on the outside and white on the inside. It is an upright plant with 30 to 80 cm of height, which has a ramified, hairy, brittle stem that exudes a yellow latex with strong odor and bitter taste. The leaves are big, alternated, petiole, dark green in the ventral side, glaucus on the dorsal side. The flowers are small, 6 to 8 mm wide, yellow, displayed as a false umbrella containing from two to seven flowers with irregular stalks, comprehending two yellow, deciduous serpals, and four petals also yellow; displaying a lot of stamen (from 16 to 24) and an ovary with two carpels, with a very short stylus. The fruits are bivalve linear capsules, 2.5 to 5.0 mm long, dehiscent from the basis and the seeds are placed in two rows, they are almost black and have an arched aryl in the shape of a crest. The root is not very thick, long, funnel-shaped, ending in a thin tip; it is frequently ramified, fissured, fibrous, spongy and brown-red, on the outside. It is densely covered by small secondary, dark and fibrous roots. Its transversal section is light yellow or orange and exudes intense yellow or brick-red, tart-flavored and spicy latex.

DRUG DESCRIPTION
- The drug displays the characteristics previously detailed in *Plant description*.

MOTHER TINCTURE PREPARATION
- Proceed according to what was described in *Preparation of the plant origin mother tincture* **(10.1)**. The mother tincture of *Chelidonium* is prepared through maceration or percolation, so that the alcoholic content, both throughout and at the end of the extraction, is 45% (v/v), according to the general technique of mother tincture preparation.

MOTHER TINCTURE CHARACTERISTICS
- Dark brown liquid, with weak odor and bitter taste, which contains, at least, 0.015% of total alcaloids expressed in chelidonine,

IDENTIFICATION
A. Evaporate 1mL of the mother tincture in water bath. Add to the residue, 0.5 mL of hydrochloric acid at 5% (v/v). Add some drops of the potassium bismuth iodide SR2. Observe the formation of an orange precipitate.
B. Repeat the reaction described in test **A**. of *Identification*, substituting the potassium bismuth iodide SR2 with the mercury potassium iodide ST. Observe the formation of a dark brown precipitate.
C. To 2 mL of the mother tincture, add 2 mL of chloramine-T solution at 10% (p/v). The color lime yellow develops.

This translation does not replace the portuguese version.

D. To 1 mL of the mother tincture, add 10 mL of purified water and 1 mL of ammonium hydroxide. To this mixture, add 3 mL of ethyl ether. Stir it up. Examine under ultraviolet light (365 nm). Observe the blue fluorescence in the upper phase.

E. Proceed according to what was described in *Thin Layer Chromatography* **(5.2.17.1) FB 5**, using silica-gel as support, and a mixture of 1-butanol, glacial acetic acid and purified water (4:1:1) as the mobile phase. Apply 20μL of the mother tincture to the plate. Develop a chromatogram for a 15 cm path. Remove the plate, let it air dry. Examine under ultraviolet light (365 nm). The chromatogram displays a stain with blue fluorescence and Rf close to 0.15; another one with greenish-yellow fluorescence with Rf close to 0.30, and a third one with intense yellow fluorescence and Rf close to 0.35; one with a greenish-yellow fluorescence and Rf close to 0.45; a stain with blue fluorescence and Rf close to 0.85; another one with brown-reddish fluorescence and Rf close to 0.90; and a last one with red fluorescence and Rf close to 0.95. Next, nebulize the plate with potassium bismuth iodide SR2 and sulphuric acid solution 0.1. *M*. Examine under natural light. The stain with the Rf closest to 0.35 appears in orange. Another stain with Rf 0.65 also in orange and other two stains with the same color and Rfs close to 0.45 and 0.70 can be displayed.

PURITY TESTS

- **Ethanol title.** Must be between 40% and 50% (v/v).
- **Dry residue.** Must be equal or superior to 1,2% (p/v).

DOSAGE

- Weigh 20 g of the mother tincture in a previously crucible porcelain capsule. Evaporate the ethanol and add 10 mL of sulphuric acid solution at 10% (p/v). Heat up in boiling water bath for 20 minutes. Weigh the resulting liquid and adjust again to 20 g with purified water. Filter and wash the filter with sulphuric acid at 10% (p/v). Make the solution alkaline with the sufficient amount of anhydrous sodium sulfate. Filter and reduce the extracts to a decimal of the initial value. Add to the resulting amount, 20 mL of sulphuric acid 0.01 *M* SV. Eliminate the remaining ethyl ether through evaporation and, next, add 20 mL of purified water. Titrate the excess of sulphuric acid with sodium hydroxide 0.01 *M* SV, using as the indicator the methyl red SI. Each mL of sulphuric acid 0.01 *M* SV is equivalent to 3.5336 mg of total alcoids expressed in chelidonine.

PACKAGING AND STORAGE

- In a neutral and amber glass recipient, very well closed and away from the light and heat.

DERIVED FORMS

- **Starting point.** Mother tincture.
- **Inert ingredient.** From 1 CH until 3 CH or 1 DH until 6 DH, use the same alcoholic content as the mother tincture. For the other dynamizing procedures, use the general preparation rule for derived pharmaceutical forms.
- **Method.** *Hahnemannian method* **(11.1)**, *Korsakovian method* **(11.2)**, *Continuous flow method* **(11.3)**.
- **Dispensation.** From the mother tincture, following the main dispensation rule.
- **Packaging and storage.** In a neutral and amber glass recipient, very well closed and away from the light and heat.

This translation does not replace the portuguese version.

CUPRUM METALLICUM

- Cu; 63,55 [*7440-50-8*]
- It has, at least, 99.5% of Cu, after drying in the oven at 105 °C, until constant weight.

HOMEOPATHIC SYNONYM
- Cuprum.

CHEMICAL NAME
- Copper, Metallic copper.

DESCRIPTION
- **Chemical-physical characteristics.** Light red, shiny, malleable metal, very thin wire or blade or powder. It is not attacked by the hydrochloric and sulphuric acids when diluted; it is easily attacked by the diluted nitric acid and by the concentrated sulphuric acid and at heat. It is not altered in the presence of dry air. However, in the presence of atmospheric humidity and carbon dioxide, it is easily covered with a protective layer of basic green copper carbonate. When it is lightly heated up, in contact with air, it is covered by a layer of red cuprous oxide. When it is heated red hot and with no contact with air, the copper is oxidized, forming the black cupric oxide, which detaches in the form of small blades. In contact with the hydrogen sulphide, it forms, with the metal, a copper sulphide cover that sometimes is displayed in the color blue.
- **Solubility.** Insoluble in water, insoluble in ethanol. Practically insoluble in alkaline means.
- **Incompatibilities.** Nitric acid, ammonium hydroxide.

Physical-chemical constants.
- *Fusion point* **(5.2.2) FB 5**: 1083 °C.

IDENTIFICATION
A. Small sample amount, humidified with hydrochloric acid, in a platinum handle, taken to the non-illuminating zone of the Bunsen burner's flame,
B. To 0.05 g of the metal, add 10 mL of concentrated hydrochloric acid. To this solution, add excess of ammonium hydroxide. A light blue color develops.
C. To 0.1 g of the metal, add 1 mL of concentrated nitric acid. Observe the detachment of brown steams.
D. Prepare the *Solution (1)* described below.
  – *Solution (1)*: to 0.05 g of the metal, add nitric acid solution 8 *M* in a sufficient amount to dissolve it completely and dilute with water until it completes 10 mL.
  – To 2 mL of *Solution (1)*, add aqueous solution of ammonium hydroxide at 10% (p/v). Observe, initially, the formation of a sky blue precipitate of a basic salt which is soluble in the excess of the reactive, originating an intense blue solution.
E. To 2 mL of *Solution (1)*, described in the **D.** test of *Identification*, add five drops of the potassium ferrocyanide solution at 1% (p/v). Observe the formation of a brown-red precipitate.

PURITY TESTS
- **Metallic impurities and arsenic.** Prepare the *Solution (1)* described below.

This translation does not replace the portuguese version.

- *Solution (1)*: to 5 g of the divided metal, add nitric acid at 32% (v/v) in sufficient amounts to dissolve it.
- With *Solution (1)* carry out tests for detecting, respectively, the presence of arsenic **(5.3.1.1) FB 5**, lead **(5.3.1.1) FB 5** and iron **(5.3.1.1) FB 5**.

DOSAGE
- Weigh 0.25 g of the metal, dissolve it in sufficient quantity of concentrated sulphuric acid, at heat; dilute with purified water until it completes the volume of 50 mL. Add 3 g of potassium iodide and 5 mL of concentrated acetic acid. Titrate the iodine released with sodium thiosulphate. 0.1 *M* SV, using a starch solution at 2% (p/v) as an indicator. Each mL of sodium thiosulphate consumed is equivalent to 0.006354 g of Cu.

PACKAGING AND STORAGE
- In a hermetically closed recipient, away from gases and air humidity.

DERIVED FORMS
- **Starting point.** Metallic copper.
- **Inert ingredient.** Lactose in the first three centesimal and six first decimal; ethanol in several concentrations for the following.
- **Method.** *Hahnemannian method* **(11.1)**, *Korsakovian method* **(11.2)**, *Continuous flow method* **(11.3)**.
- **Dispensation.** From 3 DH trit. or 2 CH trit.
- **Packaging and storage.** In a neutral, amber and very closed recipient.

This translation does not replace the portuguese version.

CYCLAMEN EUROPAEUM

- *Cyclamen purpurascens* Miller – PRIMULACEAE

HOMEOPATHIC SYNONYM
- Artanita cyclamen, Cyclamen officinalis, Cyclamen orbiculare.

PART USED
- Root.

PLANT DESCRIPTION
- *Cyclamen purpurascens* Miller is a perennial plant with a large and long root and a brown globular on the outside displaying several small roots. The stem is 8 to 10 cm high, upright, with radical, long, petiolate, orbicular and heart-shaped leaves, dented and dark green in the upper side and purple or violet inside with white stains on the edges. The flowers are aromatic, purple or rarely white and red; corolla with five oblong lobes welded to the base and reflected back, displaying five stamen and a non-salient style. The berries are involved by a capsule.

DRUG DESCRIPTION
- The root of *Cyclamen purpurascens* is spherical, sort of flattened with about 2 cm of thickness and 3 to 5 cm of diameter, hard of the outside and dark brown. The surface of the base displays long, brown and filamentous roots. Internally, it has is white and has a fleshy consistency.

MOTHER TINCTURE PREPARATION
- Proceed according to what was described in *Preparation of the plant origin mother tincture*. The mother tincture of *Cyclamen europaeum* is prepared through maceration or percolation, so that the alcohol content, both throughout and at the end of the extraction, is 45% (v/v), according to the general technique of mother tincture preparation

MOTHER TINCTURE CHARACTERISTICS
- Yellow liquid with weak particular odor and not very accentuated bitter taste.

IDENTIFICATION
A. To 1mL of the mother tincture, add 1 mL of 0.1 g resorcinol solution in 10 mL of hydrochloric acid and heat up in water bath for 1 minute. A strong red color develops.

B. Evaporate 0.1 mL of the mother tincture in water bath. Add to the residue three drops of sulphuric acid at 10% (p/v). Observe, initially, the development of a orange-red color, which starts with red and, afterwards, goes to an intense violet color.

C. To 2 mL of the mother tincture, add 2 mL of purified water. Observe turbidity. Stir it up vigorously. Observe the formation of abundant foam that persists for about 1 hour.

D. Proceed according to what was described in *Thin layer chromatography* **(5.2.17.1) FB 5**, using silica gel as a support, and a mixture of 1-butanol, acetic acid and water (4:1:1) as the mobile phase. Apply 20 μL of the mother tincture and the *Standard solution*, recently prepared, to the plate, as described below.
- *Standard solution*: dissolve 10 mg of escine in ethanol at 70% (v/v) and complete the volume to 10 mL with the same solvent.

This translation does not replace the portuguese version.

- Develop the chromatogram for a 15 cm path. Remove the plate and let it air dry. Examine it under ultraviolet light (365 nm). Regarding the chromatogram obtained with the mother tincture, usually two stains of blue fluorescence are observed with Rfs of 0.30 and 0.55. Nebulize the plate with antimony chloride solution at 1% (p/v) in chloroform and heat it oven between 105 °C and 110 °C for 10 minutes. Examine it under natural light. The chromatogram obtained with the *Standard solution* displays a light violet stain with Rf of 0.40 and the mother tincture one displays a succession of violet stains with Rfs between 0.10 and 0.60, two of them are more intense with Rfs of 0.30 and 0.40.

PURITY TESTS
- **Ethanol title.** Must be between 40% and 50% (v/v).
- **Dry residue.** Must be equal or superior to 3,5% (p/v).

PACKAGING AND STORAGE
- In a neutral and amber glass recipient, very well closed and away from the light and heat.

DERIVED FORMS
- **Starting point.** Mother tincture
- **Inert ingredient.** From 1 CH until 3 CH or 1 DH until 6 DH, using the same alcohol content for the mother tincture. For the other dynamizing procedures, follow the general preparation rule for derived pharmaceutical forms.
- **Method.** *Hahnemannian method (11.1), Korsakovian method (11.2), Continuous flow method* **(11.3)**.
- **Dispensation.** From 1 CH or 2 DH, following the general dispensation rule.
- **Packaging and storage.** In a neutral and amber glass recipient, very well closed and away from the light and heat.

This translation does not replace the portuguese version.

DULCAMARA

- *Solanum dulcamara* (L.) – SOLANACEAE

HOMEOPATHIC SYNONYM
- Solanum dulcamara, Amara dulcis, Bittersweet.

PART USED
- Whole dry plant except for the root, of *Solanum dulcamara* L.

PLANT DESCRIPTION
- *Solanum dulcamara* L is a sub-shrub with 1 to 3 m of height, it has a woody stem in the base with flexuous, climbing branches without tendrils, rolling up on their own supports. The leaves are whole, alternated and have a petiole in the basal region of the limb, the upper ones have three lobes, stipule-shaped auricules and heart-shaped base. Violet flowers with irregular summit, largely pedunculated; a calyx with five short dents, five maculated petals in the shape of a star, stamen with yellow poricidal and adnate anthers. The ovary is bicarpellary, bilocular and pluriovulate. The fruit is an ovoid, shiny, green berry and, when it is mature, it turns red. It has a sweet to bitter taste and unpleasant smell.
- The leaves of *Solanum dulcamara* L. display a heterogeneous and asymmetric mesophyll. The medium nerve region is characterized by presenting a subepidermal collenchymatous region and a fundamental parenchyma involving bicollateral vascular bundles. Idioblasts containing crystal sand may be observed.
- The stem, in a secondary structure, when cut transversally, displays a suber made up of few long cell layers of approximately rectangular contour in the tangential direction. Sometimes, we may observe the presence of epidermal remains located outside this region. The secondary cortical region or feloderm is under developed and displays cells with cellulosic walls which are thicker than the primary cortex region. Chloroplasts may be observed in the cortical region. Bags containing crystal sand may be observed throughout the whole cortical region. The endoderm is not very evident and, more internally, there is the presence of perivascular fibers placed in one or two layers provided with thick walls of reduced lumen.
- The flowmatic region is well developed and the presence of sifted plates and fellow cells may be observed. The phloem's secondary region is grooved by secondary medullary rays placed radially and constituted by a row of cells. The cambial region is very evident and the xylem is well developed and made up of vessels placed radially. The medullary rays are made up of a row of cells and connect the secondary xylem to the secondary phloem. Inside the xylem, there is the presence of an internal phloem, where the existence of some tight lumen fibers may be observed. The medullary parenchyma contains starch grains. Crystal sand bags occur in the parenchyma and phloem regions.

DRUG DESCRIPTION
- The drug is made up of the whole dry plant, except for the root. The stem is displayed in fragments that are 5 to 10 cm long and made up of five under prominent gables. It displays a wrinkled surface and scars left by fallen leaves. Generally, they are fistulous and are covered by a fat cover easily separated by friction. The leaves are displayed crumpled and bearing the characteristics presented in the plant description.

This translation does not replace the portuguese version.

MOTHER TINCTURE PREPARATION

- Proceed according to what was described in the *Preparation of the plant origin mother tincture* **(10.1)**. The mother tincture of *Solanum dulcamara* is prepared by maceration or percolation, so the alcohol content, both throughout and at the end of the extraction, is 45% (v/v), according to the general technique of mother tincture preparation.

MOTHER TINCTURE CHARACTERISTICS

- Dark brown aromatic liquid with slightly bitter taste.

IDENTIFICATION

A. To 10 mL of purified water, add 1 mL of the mother tincture. Stir up vigorously. Observe the formation of abundant foam.

B. Evaporate 1 mL of the mother tincture. Treat the residue with 0.5 mL of hydrochloric acid at 5% (v/v). Add a few drops of the potassium bismuth iodide SR2. Observe the formation of an orange precipitate.

C. Repeat the previous operation. To the residue treated with hydrochloric acid at 5% (v/v), add a few drops of mercury potassium iodide SR. Observe the formation of a white precipitate.

D. Proceed according to what was described in *Thin layer chromatography* **(5.2.17.1) FB 5**, using G silica gel as a support, and a mixture of 1-butanol, glacial acetic acid and purified water (4:1:1) as the mobile phase. Apply 20 μL of the mother tincture to the plate. Develop the chromatogram for a 10 cm path. Remove the plate and let it air dry. Examine under ultraviolet light (365 nm). The chromatogram usually shows a fluorescent greenish-yellow stain with Rf between 0.40 and 0.50; one or two fluorescent dark brown stains with Rf between 0.40 and 0.50; one or two fluorescent dark brown stains with Rf close to 0.55, another fluorescent blue and with Rf between 0.85 and 0.90; and a last stain with red fluorescence and Rf close to 0.95. On a second stage, nebulize the plate with diluted potassium bismuth iodide SR. Examine it under natural light. The chromatogram displays two orange stains, weak in intensity, and with Rfs close to 0.40 and 0.50.

- Develop a second chromatogram with the same conditions as previously. Nebulize the plate with a valinin-phosporic reagent. Heat up the plate at 120 °C for 15 minutes. Examine under ultraviolet light (365 nm). The chromatogram displays a brown fluorescent stain with Rf close to 0.30 and other three or four fluorescent yellow stains with Rf values between 0.35 and 0,65.
- Develop a third chromatogram in each thin layer of G silica gel, having as the mobile phase, the solvent mixture made up of chloroform and methanol (9:1). Let the plate air dry. Nebulize it with antimony chloride solution at 1% (p/v) in chloroform. It displays a stain with Rf 0.84.

PURITY TESTS

- **Ethanol title.** It must be between 40% and 50% (v/v).
- **Dry residue.** It must be equal or superior to 1,2% (p/v).

PACKAGING AND STORAGE

- In a neutral and amber glass recipient, very well closed and away from the light and heat.

DERIVED FORMS

- **Starting point.** Mother tincture.

This translation does not replace the portuguese version.

- **Inert ingredient.** From 1 CH until 3 CH or 1 DH until 6 DH, using the same alcohol content as the mother tincture. For the other dynamizing procedures, follow the general preparation rule of derived pharmaceutical forms.
- **Method.** *Hahnemannian method (11.1), Korsakovian method (11.2), Continuous flow method* **(11.3)**.
- **Dispensation**. From 1 CH or 1 DH, following the general dispensation rule.
- **Packaging and storage.** In a neutral glass recipient, very well closed and away from light and heat.

This translation does not replace the portuguese version.

ECHINACEA ANGUSTIFOLIA

- *Echinacea angustifolia* (DC.) – ASTERACEAE

HOMEOPATHIC SYNONYM
- Echinacea, Echinacea.

PART USED
- Whole plant.

PLANT DESCRIPTION
- *Echinacea angustifolia* DC. is a perennial herb with a strong radicle root, and an average height that varies from 30 to 60 cm, possibly reaching, however, 1 m of height. The leaves are alternated, lanceolate, elliptical, gradually attenuated at the base, with about 20 cm of length and 4 cm of width, with curvilinear nerves and displays not very abundant piles. The basal leaves have a long petiole. The influorescence is in a lonesome chapter located at the end of the stem, with a diameter of 1 to 3 cm and upright bracts. The peripheral flowers are pale pink, rarely white, with 2 to 8 cm of width, sort of bent over the chapter.

DRUG DESCRIPTION
- The drug is constituted by the whole dry plant.

MOTHER TINCTURE PREPARATION
- Proceed according to what was described in the *Preparation of the plant origin mother tincture* **(10.1)**. The mother tincture of *Echinacea angustifolia* is prepared by maceration or percolation, so that the alcohol content, both throughout and at the end of the extraction, is 65% (v/v), according to the general technique of mother tincture preparation.

MOTHER TINCTURE CHARACTERISTICS
- Green liquid with aromatic smell and pleasant flavor.

IDENTIFICATION
A. To 1 mL of the mother tincture, add one drop of the ferric chloride at 1% (p/v). A dark green color with turbidity develops.
B. To 1 mL of the mother tincture, add two drops of the reagent obtained at the moment of the use formed by equal parts of ferric chloride at 1% (p/v) and potassium ferrocyanide at 1% (p/v). A dark green color develops.
C. To 2 mL of the mother tincture, add two drops of the Tollens reagent. Heat up in boiling water bath for 1 minute. Observe the formation of a black precipitate.
D. To 2 mL of the mother tincture, add five drops of alkaline cupric tartrate SR. While cool, the color green-yellow develops. Heat up in boiling water bath for 2 minutes. The color ochre yellow develops with turbidity.
E. To 2 mL of the mother tincture, add five drops of silver nitrate solution at 1% (p/v). Heat up in boiling water bath for 1 minute. Observe the development of a dark gray color.
F. To 2 mL of the mother tincture, add three drops of ninhydrin solution at 0,1% (p/v). Heat up in boiling water bath for 2 minutes. The color violet develops.
G. To 1 mL of the mother tincture, add five drops of potassium hydroxide solution at 30% (p/v). The color yellow develops and intensifies gradually until it reaches the color amber-yellow.

This translation does not replace the portuguese version.

H. Observe aliquot of the mother tincture under ultraviolet light (365 nm). Observe a pink fluorescence.

I. Proceed according to what was described in *Thin layer chromatography* **(5.2.17.1) FB 5**, using G silica gel as a support, and a mixture of 1-butanol, glacial acetic acid and water (40:10:10) as the mobile phase. Apply 20 μL of the mother tincture to the plate. Develop the chromatogram for a 10 cm path. Remove the plate and let it air dry. Examine it under ultraviolet light (365 nm). The chromatogram usually displays a succession of stains with blue fluorescence and comprehended between the Rfs 0.20 and 0.65 and one or two red stains with not very clear separation and Rf close to 0.09. Another brown stain may appear, with Rf close to 0.45. Next, nebulize the chromatographic plate with anisic aldehyde solution, heating it up in oven afterwards until temperatures between 100 °C e 105 °C, for 10 minutes. Examine it under visible light. Observe a dark green stain with Rf close to 0.35, an orange one with Rf close to 0.40, a third grayish one with Rf close to 0.50 and two or three others, which are violet and with Rfs between 0.80 e 0.95.

- Develop a second chromatogram in the same conditions as the previous one. Nebulize the chromatoplate with an aniline phthalate solution, heat up in oven to temperatures between 100 °C and 105 °C for about 20 minutes. Examine it under visible light. Observe only one brown stain with Rf close to 0.30.
- Develop a third chromatogram in the same conditions as the previous ones, however use phase the mixture of chloroform and methanol (9:1) as the mobile. Remove the plate and let it air dry. Next, nebulize the chromatoplate with an antimony chloride solution at 1% (p/v) in chloroform. Examine it under ultraviolet light (365 mn). Observe two stains with Rfs close to, respectively, 0.22 and 0.87.

PURITY TESTS

- **Ethanol title.** It must be between 60% and 70% (v/v).
- **Dry residue.** It must be equal or superior to 0.7% (p/v).

PACKAGING AND STORAGE

- In a neutral, amber glass recipient, hermetically closed and away from the light and heat.

DERIVED FORMS

- **Starting point.** Mother tincture.
- **Inert ingredient.** In the first three centesimal dynamizations and six first decimal dynamizations, use the same alcohol content as the mother tincture.
- **Método.** *Hahnemannian method (11.1), Korsakovian method (11.2), Continuous flow method* **(11.3)**.
- **Dispensação.** From 1 CH and 1 DH, ethanol will be used with the same ethanolic title as the mother tincture, in the first three dynamizations for the centesimal scale and the first six ones for the decimal scale. From there, use a hydroalcoholic solution at 30% (p/p).
- **Packaging and storage.** In a neutral and amber glass recipient, very well closed and away from the light and heat.

This translation does not replace the portuguese version.

ETHYLICUM

- C_2H_6O; 46,07 [*64-17-5*]
- Contains, at least, 95.1% (v/v), which corresponds to 92.55% (p/p), and, a maximum of 96.9%
- (v/v), which corresponds to 95.16% (p/p) of C_2H_6O at 20 °C, calculated from the relative density using the *Alcoholmetric table (20 °C)* **Appendix C**. For absolute ethyl alcohol, it contain at least
- 99.5% (v/v), which corresponds to 99.18% (p/p) of C_2H_6O at 20 °C, calculated from the relative density using the *Alcoholmetric table (20 °C)* **Appendix C**.

HOMEOPATHIC SYNONYM
- Alchoolum.

CHEMICAL NAME
- Ethyl alcohol.

DESCRIPTION
- **Physical Characteristics.** Colorless, clear, volatile, flammable and hygroscopic liquid.
- **Solubility.** Miscible with water and methylene chloride.

Physical-chemical constants.
- *Relative density* **(5.2.5) FB 5**: 0.805 to 0.812, determined at 20 °C. For absolute ethyl alcohol, not more than 0.793, determined at 20 °C.

IDENFICATION
- The infrared absorption spectrum **(5.2.14) FB 5** of the sample displays the maximum values of absorption only in the same wave lengths and with the same relative intensities of those observed in the SQR ethanol spectrum.

PURITY TESTS
- **Solution's Clarity (5.2.25) FB 5.** Prepare the solutions and suspensions described below.
  - *Hydrazine solution*: transfer 1 g of hydrazine sulfate to a 100 mL volumetric balloon, dissolve and complete the volume with water and stir it up. Let it rest for 4 to 6 hours.
  - *Methenamine solution:* transfer 2.5 mg of methenamine to a 100 mL volumetric balloon, add 25 mL of water and stir until it dissolves.
  - *Primary opalescent suspension*: transfer 25 mL of the *Hydrazine solution* to the 100 mL volumetric balloon containing the *Methenamine solution*. Stir and let it rest for 24 hours.

Note: *the Primary opalescent suspension is stable for 2 months, if kept in a closed glass recipient without flaws. The suspension can adhere to the glass and must be stirred before use.*
  - *Opalescence standard*: transfer 15 mL of the *Primary opalescent suspension* to a 100 mL volumetric balloon, complete the volume with water and stir.

Note: *the Opalescence standard must not be used 24 hours after the preparation.*
  - *Reference suspensions*: transfer 5 mL of the *Opalescence standard* to a 100 mL volumetric balloon, complete the volume with water and stir to obtain the *Reference suspension*.

This translation does not replace the portuguese version.

Transfer 10 mL of this solution to another 100 mL balloon, complete with water and stir to obtain the *Reference Suspension B*.

– *Sample A solution*: sample to be examined.
– *Sample B solution*: dilute the *Sample A solution* to 20 mL of water and let it rest for 5 minutes before use.
– *Procedure*: transfer a portion of the *Sample A Solution* and the *Sample B Solution* to colorless and transparent glass tubes with an internal diameter between 15 mm e 25 mm, in order to obtain approximately 40 mm of depth. Transfer to tubes with a similar volume as the *Reference Suspension A*, *Reference Suspension B* and water. Compare the *Sample A Solution, Sample B Solution, Reference Suspension A*, *Reference Suspension B* and water, using dark background and light. The *Sample A Solution* and *Sample B Solution* have the same clarity as the water or do not display bigger opalescence than the *Reference Suspension A*.

Color of liquids (5.2.12) FB 5. Prepare the solutions described below.

- *Standard stock solution*: combine 3 mL of *Ferric chloride base solution*, 3 mL of *Cobalt chloride II base solution*, 2.4 mL of *Cupric sulfate base solution* and 1.6 mL of diluted hydrochloric acid (10 mg/mL).
- *Standard solution*: transfer 1 mL of *Standard stock solution* to a 100 mL volumetric balloon, complete the volume with diluted hydrochloric acid (10 mg/mL) and stir. Use this solution right after preparing it.
- *Procedure*: transfer a portion of the *Standard solution* to a colorless and transparent glass tube with an internal diameter between 15 and 25 mm, in order to obtain approximately 40 mm of depth. Transfer the same sample volume to a similar tube and the same quantity of water to another tube. The *Sample A Solution* doesn't have a more intense color than the *Standard solution*.
- **Acidity or alkalinity** Add 20 mL of water, free from carbon dioxide, to 20 mL of the sample and add 0.1 mL of phenolphthalein SI. The solution must be colorless. Add 1 mL of sodium hydroxide 0.01 *M*. The solution must become pink (30 ppm, expressed as acetic acid).
- **Light absorption.** Record the ultraviolet absorption spectrum of the sample between 200 nm and 400 nm using a 1 cm optical path slide, using water as the white. Maximum absorbance of 0.08 in 240 nm, 0.06 between 250 nm and 260 nm and 0.02 between 270 nm and 340 nm.
- **Non-volatile residue limit.** Evaporate 100 mL of sample in water bath and dry the residue at 105 °C for 1 hour. Cool in mortar and weigh. The residue must not weigh more than 2.5 mg. A maximum of 0.025%.
- **Organic impurities.** To 5 mL of the sample, add purified water, little by little, on the recipients' walls, until it completes 50 mL. The mixture should not even become slightly turbid.

DOSAGE

- Determine the quantity of C2H6O at 20 °C, from the relative density using the *Alcoholmetric table (20 °C)* **Appendix C**.

PACKAGING AND STORAGE

- In very closed recipients.

This translation does not replace the portuguese version.

DERIVED FORMS

- **Starting point.** Ethylic alcohol at 96% (v/v).
- **Inert ingredient.** Purified water. Observation: extemporaneous preparation.
- **Method.** *Hahnemannian method (11.1), Korsakovian method (11.2), Continuous flow method*
- **(11.3)**.
- **Dispensation.** From 1 DH or 1 CH.
- **Packaging and storage.** In a neutral, amber and very closed recipient.

This translation does not replace the portuguese version.

FERRUM METALLICUM

- Fe; 55,85 [*7439-89-6*]
- Contains, at least, 90% of iron in relation to the substance dried in over at 105 °C, until constant weight.

HOMEOPATHIC SYNONYM
- Ferrum reductum, Ferrum purum, Ferrum.

CHEMICAL NAME
- Iron, Metallic iron.

DESCRIPTION
- **Physical-chemical characteristics.** Extremely thin, dark grey, odorless, malleable powder. Stable when exposed to dry air, quickly changeable when heated red hot and slowly changeable, in the presence of humid air, turning into hydrated ferric oxide.
- **Solubility.** Insoluble in water and in ethanol; soluble in mineral acids, with the release of hydrogen.

IDENTIFICATION

A. **A.** To 2 mL of *Solution A*, as described below, add five drops of aqueous solution of potassium ferrocyanide at 1% (p/v). Observe a dark blue color.
  – *Solution A*: treat 0.1 g of the sample with 2.5 mL of hydrochloric acid diluted at 10% (v/v) and dilute with equal quantity of purified water.

B. To 2 mL of *Solution A* add, drop by drop, ammonium sulfate SR. Observe the formation of a black precipitate.

PURITY TESTS
- **Arsenic (5.3.2.5) FB 5.** Weigh 2 g, transfer to the recipient of the device dedicated to determine arsenic, add 20 mL of stannous chloride SR and, immediately, adapt the device's tube. Proceed according to what was described in *Limit trial for arsenic*. A maximum of 0.0005% (5 ppm).
- **Heavy metals (5.3.2.3) FB 5.** Use *Method I*. Weigh, exactly, 1 g and treat with the mixture of 10 mL of hydrochloric acid and 25 mL of purified water, heating up in water bath; evaporate until dryness, dissolve the residue in about 20 mL of purified water, adding 1 mL of purified water and 1 mL of hydrochloric acid, if necessary; transfer to the 50 mL Nessler tube with 25 mm of outside diameter, and proceed as described in *Limit trial for heavy metals*. A maximum of 0.0010% (10 ppm).
- **Insolubles in sulfuric acid.** Weigh exactly about 2 g and introduce, little by little, in a mixture made up of 5 mL of sulfuric acid and 50 mL of purified water; heat up moderately in water bath, if necessary, until more hydrogen is detached. Filter the insoluble residue, wash first with acidified water, containing sulfuric acid at 2% (v/v), and then with purified water until the elimination of sulfates; desiccate at 105 °C for 2 hours and weigh; the residue's weight must not be more than 0.003 g (0.15%).
- **Chloride.** Take 10 mL of the filtered *Solution B*, as described below, add 0.5 mL of nitric acid and 2 mL of silver nitrate SR: there should be no opalescence.
  – *Solution B*: stir 10 g of metallic iron with 50 mL of purified water and filter.

This translation does not replace the portuguese version.

- **Substances soluble in water.** Evaporate 10 mL of the filtered *Solution B* in a crucible porcelain capsule and desiccate the residue at 105 °C for 2 hours: the weight must not be more than 0.003 g (0.15%).
- **Sulfate.** Take 10 mL of the filtered *Solution B*, add 0.5 mL of hydrochloric acid SR and 2 mL of barium chloride SR, boil it and leave it in water bath for 15 minutes: it must not produce opalescence.

DOSAGE
- Weigh 0.25 g of metallic iron, put it in a recipient with grinded lid, add 20 mL of SR cupric sulfate previously heated, stir up for 10 minutes. Filter quickly. Wash the residue contained in the filter with a sufficient amount of purified water; acidify the filtered substance with some drops of concentrated sulphuric acid and titrate with potassium permanganate 0.02 *M* SV. Each mL of potassium permanganate 0.02 *M* SV consumed corresponds to 0.00559 g of Fe.

PACKAGING AND STORAGE
- In dry and very well closed recipients.

DERIVED FORMS
- **Starting point.** Metallic iron (Fe).
- **Inert ingredient.** Lactose in the first three centesimal and six first decimal; ethanol in several concentrations for the next ones.
- **Method.** *Hahnemannian method (11.1), Korsakovian method (11.2), Continuous flow method* **(11.3)**.
- **Dispensation.** From 1 DH trit. or 1 CH trit.
- **Packaging and storage.** In a neutral, amber, very closed recipient.

This translation does not replace the portuguese version.

FERRUM SULPHURICUM

- $FeSO_4.7H_2O$; 278,00 [*7782-63-0*]
- It contains, at least, 98.0% and, a maximum of 105.0% of $FeSO_4.7H_2O$.

HOMEOPATHIC SYNONYM
- Ferri sulphas, Sulphas ferrosus, Ferrosi sulphas, Ferrum sulphuricum oxydulatum.

CHEMICAL NAME
- Heptahydrate ferrous sulfate.

DESCRIPTION
- **Physical characteristics.** Light green crystalline power or green-blue, odorless crystals, of astringent flavor and fluorescent at dry air. They oxidize quickly when in contact with humid air, forming basic yellow-brown ferric sulfate.
- **Solubility.** Easily soluble in water, practically insoluble in ethanol.

IDENTIFICATION
- The solution obtained in *Solution aspect* responds to the ferrous ion reactions **(5.3.1.1) FB 5**.
- The solution obtained in *Solution aspect* responds to the sulfate ion reactions **(5.3.1.1) FB 5**.

PURITY TESTS
- **Solution's aspect.** Dissolve 2.5 g of sample in water free from carbon dioxide, add 0.5 mL of sulphuric *M* and dilute to 50 mL with water. The preparation obtained is not more opalescent that the *Reference suspension II* **(5.2.25) FB 5**.
- **pH (5.2.19) FB 5.** 3.0 to 4.0. Determine in sample solution at 5% (p/v) in water free from carbon dioxide.
- **Arsenic (5.3.2.5) FB 5.** Transfer 1 g of the sample to a 100 mL balloon with the rounded bottom and a distillation system. Add 40 mL of sulphuric acid 4.5 *M*, 2 mL of potassium bromide at 30% (p/v) and connect immediately in a mild flame until the sample dissolves and distillates until 25 mL of distillated material is obtained. Transfer the distillated material to the arsine generator flask and wash the condenser and other parts of the distillation system with small a portion of water, adding the washing waters to the arsine generator flask. Stir up the flask with circular movements, add bromine water SR until a slightly yellow color appears and dilute with water at 35 mL. Proceed according to what was described in *Spectrophotometric Method, Method I*. A maximum of 0.0003% (3 ppm).
- **Chlorides (5.3.2.1) FB 5.** Determine in 1.2 g of sample, using 1 mL of standard hydrochloric acid (HCl 0.01 *M* SV), for preparing the standard. A maximum of 0.03% (300 ppm).
- **Ferric ion.** Transfer 5 g of the sample to the Erlenmeyer with a lid and dissolve with a mixture of 10 mL of hydrochloric acid and 100 mL of water free from carbon dioxide. Add 3 g of potassium iodide, cover and let it rest away from the light for 5 minutes. Titrate the iodine released with sodium thiosulfate 0.1 *M* SV using, as an indicator, 0.5 mL of SI starch, adding it close to the final point. Carry out a trial in white and do the necessary corrections. A maximum of 4.5 mL of sodium thiosulfate 0.1 *M* SV are used in the titration (0.5%).
- **Manganese.** Dissolve 1 g of the sample in 40 mL of water, add 10 mL of nitric acid and boil until the detachment of red steams. Add 0.5 g of ammonium persulphate and boil it for 10 minutes. Eliminate any pink color that may appear occasionally adding sodium sulfate solution at 5% (p/v), drop by drop. Boil the sulphur dioxide until the odor disappears, boil for

This translation does not replace the portuguese version.

1 minute and cool down at room temperature. The solution obtained is more intensely colored than the standard prepared in the same conditions, using 1 mL of potassium permanganate 0.02 *M* SV and the same quantities of reagents (0.1%).

- **Zinc.** Dissolve 1 g of the sample in 10 mL of hydrochloric acid SR, add 2 mL of concentrated hydrogen peroxide and boil it until it reduces the volume to 5mL. Cool down, dilute to 20 mL of hydrochloric acid SR, transfer to a hopper and stir for 3 minutes with three portions of 20 mL of saturated, recently distillated methylisobutylketone with 1 mL of hydrochloric acid (prepared by stirring up 100 mL of recently distillated methylisobutylketone with 1 mL of hydrochloric acid SR.) Let it rest, separate the aqueous layer and reduce its volume to half in water bath. Cool down, transfer quantitatively to a 25 mL volumetric balloon and complete the volume with water. To 5 mL of this solution, add 1 mL of potassium ferrocyanide SR and dilute to 13 mL with water. After 5 minutes, any turbidity developed is not more intense that the one produced by the mixture of 10 mL of zinc standard solution (10 ppm Zn), 2 mL of hydrochloric acid SR and 1 mL of potassium ferrocyanide SR. A maximum of 0.05% (500 ppm).
- **Heavy metals (5.3.2.3) FB 5.** Prepare the *Solution (1)* described below. Transfer 30 mL of the *Solution (1)* to the Nessler tube at 50 mL and adjust the pH between 3.0 and 4.0 with the ammonium hydroxide *6 M* or acetic acid *M*. Add 2 mL of pH 3.5 acetate buffer, dilute with water to 40 mL and homogenize. For the preparation of the standard, transfer 15 mL of the *Solution (1)* to the Nessler tube at 50 mL, dilute to 25 mL with water, adjust the pH between 3.0 and 4.0 with ammonium hydroxide *6 M* or acetic acid *M*, add 2 mL of pH 3.5 acetate buffer, 3 mL of *Lead standard solution (10 ppm Pb)*, dilute to 40 mL with water and homogenize. To the standard and the sample, add 10 mL of hydrogen sulfide SR, complete the volumes with water and homogenize. Let it rest for 2 minutes. Observe the tubes from top to bottom, on a white background. Any brown color developed in the sample's preparation is not more intense that the one developed while preparing the standard. A maximum of 0.005% (50 ppm).
  - *Solution (1)*: dissolve 2 g of the sample in a mixture of 1 mL of sulphuric acid SR and 40 mL of water. Add 0.05 g of hydroxylamine hydrochloride, boil it for 1 minute. Cool it down to room temperature, transfer quantitatively to the 50 mL volumetric balloon with the help of water and complete the volume with the same solvent.

DOSAGE

- Dissolve, exactly, about 0.5 g of the sample in a mixture of 25 mL of sulphuric acid *M* and 25 mL of water free from carbon dioxide. Add two drops of ferroin SI and titrate immediately with ammonium cerium sulfate 0.1 *M* SV, until it turns orange-red to pale-green. Each mL of ammonium cerium sulfate 0.1 *M* SV is equivalent to 27.801 mg of heptahydrate ferrous sulfate ($FeSO_4.7H_2O$) and to 5.585 mg of elementary iron (Fe).

DERIVED FORMS

- **Starting point.** Ferrous sulfate.
- **Inert ingredient.** Lactose in the first three centesimals and six first decimals; ethanol in several concentrations and posterior dynamizations.
- **Method.** *Hahnemannian method (11.1), Korsakovian method (11.2), Continuous flow method* **(11.3)**.
- **Dispensation.** From 1 DH trit. or 1 CH trit.
- **Packaging and storage.** In a very well closed, neutral, amber recipient.

This translation does not replace the portuguese version.

GELSEMIUM

- *Gelsemium sempervirens* (L.) Persoon – LOGANIACEAE

HOMEOPATHIC SYNONYM
- Gelsemium sempervirens, Bignonia sempervirens, Gelsemium luteum odoratum.

PART USED
- Rhizomes and dry roots.

PLANT DESCRIPTION
- Creeping, woody, perennial shrub with purple stem and whole, opposed, shortly petiolated, oval and spear-shaped or simply spear-shaped leaves. Axilliary racemes with one to six aromatic yellow funnel-shaped or trumpet-shaped flowers; calyx with five interwoven lacing, funnel-shaped corolla with five lobes of interwoven pre-flowering. The stamen are epipetalous and they are five and the ovary is upper and bilocular. The fruit are capsular, septicidal, flat, bilocular, and contain several winged seeds in each one of the cavities.

DRUG DESCRIPTION
- The rhizome of *Gelsemium sempervirens* is cylindrical and usually appears in pieces with 3 to 20 cm of length and 3 to 30 mm of diameter, irregularly recurved and sometimes branched; its external surface is light brown-yellow, wrinkled, grooved lengthwise with purple streaks and with transversal cracks. Its transversal section displays thin, brown or brown-yellow cask, strongly adherent to the woody cylinder. The rhizome brings, directly or over its thin stolon, the rest of brown-yellow articulated stems, of 2 mm of diameter, as well as very hard roots with 1 to 2 cm of diameter direct or twisted and with variable length. The thicker roots are rarely branched and display stringy yellow and very resistant radicles, or scars that correspond to its insertion point. Its internal surface is very wrinkled, cleft, grooved lengthwise and yellow-grey or light brown-yellow; its transversal section is distinguished from the rhizome due to the absence of medulla. The plant has a soft odor and a very pronounced bitter taste. Under a very thick suber with some woody cells, the rhizome displays the cortical regional with several layers of parenchyma cells that contain starch grains, involving smalls groups of fibers and sclerous cells. The phloem is very developed, it contains sclerenchymatous fibers, and is divided in caps by the medullar rays very rich in calcium oxalate prismatic crystals, and containing tangential strips of obliterated sieved tissue. The xylem is made up of fibers with very thick walls and lignified by parenchyma, tracheids and several vessels with aerial pores, usually isolated. The xylematic region is divided into cuneiform beams by very large medullar rays, made up of rectangular cells of thick and pointy walls that contain starch. The internal phloem is very evident and formed by sieved tubes, fellow cells and phloem parenchyma. The medullar parenchyma occupies the central zone and is not very developed being more evident in the less calibrous rhizomes. The rhizome's structure does not differ from the one in the roots, only by the existence of a central medulla and the presence of sclerous cells and sclerenchymatous fibers in its cortical layer.

This translation does not replace the portuguese version.

MOTHER TINCTURE PREPARATION

- Proceed according to what was described in *Preparation of the plant origin mother tincture* **(10.1)**. The mother tincture of *Gelsemium sempervirens* (L.) Persoon is prepared by maceration or percolation, so that the alcohol content, both throughout and at the end of the extraction, is 65% (v/v), according to the general technique of mother tincture preparation.

MOTHER TINCTURE CHARACTERISTICS

- Yellow liquid with aromatic odor and bitter and slightly spicy flavor.

IDENTIFICATION

- To 1 mL of the mother tincture, add 10 mL of purified water and stir intensely. Observe the formation of abundant foam.
- The preparation of the previous item, when observed under ultraviolet light (365 nm), displays blue fluorescence.
- To 0.2 mL of the mother tincture, add 5 mL of ethanol at 50% (v/v) and a drop of concentrated ammonium hydroxide. At daylight, the solution display a yellow color and, under ultraviolet light (365 nm), observe a turquoise fluorescence.
- Evaporate 2 mL of the mother tincture in water bath. Treat the residue with 1 mL of hydrochloric acid 5% (v/v). To the solution, add some drops of mercury potassium iodide SR. A white-yellow precipitate develops.
- Proceed according to what was described in the test **D.** of *Identification*, substituting the mercury potassium iodide SR by the potassium bismuth iodine SR2. An orange precipitate develops.
- Proceed according to what was described in *Thin layer chromatography* **(5.2.17.1) FB 5**, using G silica gel as a support, and a mixture of 1-butanol, glacial acetic acid and purified water (4:1:1) as the mobile phase. Apply 20 μL of the mother tincture to the plate. Develop the chromatogram for a 10 cm path. Remove the plate and let it air dry. Examine under ultraviolet light (365 nm). The chromatogram displays two blue fluorescent stains with Rfs close to 0.35 and 0.55, another one with blue-violet fluorescence with Rfs close to 0.65 and the last one with blue fluorescence and Rfs close to 0.90. Next, nebulize the plate, successively, with the *p*-dimethylaminobenzaldehyde at 2% (p/v) in ethanol 96% (v/v) and with sulphuric acid at 10% (p/v). Heat up the chromatoplate in oven at temperatures between 100 °C and 105 °C for 5 minutes. Examine under natural light. The chromatogram displays fours grey-violet stains with Rfs close to 0.25, 0.35, 0.55 and 0.95.
- Develop a second chromatogram in the same conditions as the previous one. Nebulize the plate with a revealer prepared right before use and formed by equal parts of ferric chloride solution at 1% (p/v) and potassium ferrocyanide at 1% (p/v). Observe the appearance of five blue stains with Rfs close to 0.10, 0.15, 0.20, 0.40 and 0.90.

PURITY TESTS

- **Ethanol title.** Must be between 60% and 70% (v/v).
- **Dry residue.** Must be equal or superior to 0,5% (p/v).

PACKAGING AND STORAGE

- In a neutral and amber glass recipient, very well closed and away from the light and heat.

DERIVED FORMS

- **Starting point.** Mother tincture

This translation does not replace the portuguese version.

- **Inert ingredient.** From 1 CH until 3 CH or 1 DH until 6 DH, use the same alcoholic contents as the mother tincture. For the other dynamizations, follow the general preparation rule for derived pharmaceutical forms.
- **Method.** *Hahnemannian method (11.1), Korsakovian method (11.2), Continuous flow method* **(11.3)**.
- **Dispensation.** From 1 CH or 2 DH, following the general dispensation rule.
- **Packaging and storage.** In a neutral and amber glass recipient, very well closed and away from the light and heat.

This translation does not replace the portuguese version.

GINKGO BILOBA

- *Ginkgo biloba* (L.) – GINKGOACEAE

HOMEOPATHIC SYNONYM
- Ginkgo.

PART USED
- Dry leaves.

PLANT DESCRIPTION
- The *Ginkgo biloba* L. leaves are light green, from 6 to 8 cm long and 10 to 12 cm wide, in the shape of a flageliform fan displayed in a sort of deep chamfer in the upper part, providing it with a bilobed aspect. The borders are slightly crenulated and the limb has a leather consistency. The nerves diverge from the petiole fixation point that is long. They are odorless and have a slightly bitter flavor.

DRUG DESCRIPTION
- The drug is made up of the dry leaves.

MOTHER TINCTURE PREPARATION
- Proceed according to what was described in the *Preparation of the plant origin mother tincture* **(10.1)**. The mother tincture of *Ginkgo biloba* is prepared with ethanol at 65% (v/v) through maceration, according to the general technique of mother tincture preparation.

MOTHER TINCTURE CHARACTERISTICS
- Greenish-brown liquid, with herbaceous smell and weak taste.

IDENTIFICATION
A. To 1 mL of the mother tincture, add one drop of ferric chloride solution at 10% (p/v). A dark green color develops.
B. To 1 mL of the mother tincture, add two drops of the Tollens reagent. Observe a cold reduction with dark grey or black precipitate.
C. To 2 mL of the mother tincture, add two drops of alkaline cupric tartrate SR. Observe a cold reduction with the development of a green-yellow color. Heating up in boiling water bath, the color turns into dark green.
D. To 1 mL of the mother tincture, add two drops of ninhydrin solution at 1% (p/v) in ethanol at 96% (v/v). Heat up in boiling water bath for 2 minutes. A violet color develops.
E. To 1 mL of the mother tincture, add two drops of the silver nitrate solution at 1% (p/v). Observe the formation of a brown-red precipitate that, when heated up in boiling water bath for 1 minute, turns into dark brown.
F. To 1 mL of the mother tincture, add two drops of the mixture prepared right before use, formed by equal parts of ferric chloride solution at 1% (p/v) and solution of potassium ferrocyanide at 1% (p/v). A dark green color develops.
G. To 1 mL of the mother tincture, add fragments of metallic magnesium and 1 mL of concentrated hydrochloric acid. A brown-orange color develops.
H. To 1 mL of the mother tincture, add 50 mg of resorcinol and 1 mL of concentrated hydrochloric acid. A dark brown color develops.

This translation does not replace the portuguese version.

I. Proceed according to what was described in *Thin layer chromatography* **(5.2.17.1) FB 5**, using G silica gel as a support, and a mixture of ethyl, ethylmethylketone acetate, anhydrous formic acid and water (50:30:10) as the mobile phase. Apply, separately from the plate, 40 μL of the mother tincture and 5 µL of each one of the standard solutions, recently prepared and described below.
  – *Standard solution A*: solution of 10 mg of rutin in ethanol at 60% (v/v).
  – *Standard solution B*: dissolve 10 mg of isoquercitrin in ethanol at 96% (v/v).

- Develop the chromatogram for a 10 cm path. Remove the plate, let it air dry. Examine under ultraviolet light (365 nm). Regarding the chromatogram obtained with the standard solutions, two stains are observed with brown fluorescence and Rfs close to 0.35 and 0.65, which correspond, respectively to rutin and isoquercitrin. The chromatogram of the mother tincture displays, usually, two brown stains with Rfs close to 0.35 (rutin) e 0.55; another one light pink and fluorescent, with Rf close to 0.65 (isoquercitrin); and the last one, red, in front of it and reached by the mobile phase. Next, nebulize the plate with aminoethanol borate diphenyl SR. Examine under ultraviolet light (365 nm). Observe the presence of two stains with orange fluorescence and Rfs close to the one in the rutin standards (0.35) and isoquercitrin (0.65). The mother tincture displays two stains with yellow fluorescence and Rfs close to 0.15 and 0.20; another with orange fluorescence and Rf close to 0.35 (rutin); another one with green yellow fluorescence and Rf close to 0.45; followed by other ones with Rf at 0.60, with greenish-yellow fluorescence and Rf 0.65 with orange fluorescence (isoquercitrin); and the last one, with yellow fluorescence and Rf close to 0.95.
- Develop a second chromatogram in the same conditions as the previous one, nebulize the plate with concentrated ammonium hydroxide. Examined under ultraviolet light (365 nm), observe a stain with intense yellow fluorescence and with Rf close to 0.60.
- Develop a third chromatogram, using G silica gel, as a support and a toluene and ketone mixture (7:3), as a mobile phase. As the standard solution, use 1 mg of A-C ginkgolide dissolved in 1 mL of metanol. Develop the chromatogram for a 10 cm path. Remove the plate, let it air dry. Nebulize the plate with acetic acid, heat up the plate at 120 °C for 30 minutes and examine it under ultraviolet light (365 nm). Observe the presence of a stain with greenish-blue fluorescence with Rf close to 0.5.

PURITY TESTS
- **Ethanolic title.** Must be between 60% and 70% (v/v).
- **Dry residue.** Must be equal or superior to 1,5% (p/v).

PACKAGING AND STORAGE
- In a neutral amber glass recipient, very well closed and away from the light and the heat.

DERIVED FORMS
- **Starting point.** Mother tincture
- **Inert ingredient.** From 1 CH until 3 CH or 1 DH until 6 DH, use the same alcoholic content as the mother tincture. For the other dynamizations, follow the general rule for the preparation of the derivative pharmaceutical forms.
- **Method.** *Hahnemannian method (11.1), Korsakovian method (11.2), Continuous flow method* **(11.3)**.
- **Dispensation.** From 1 CH and 1 DH.
- **Packaging and storage.** In a neutral and amber glass recipient, very well closed, away from the light and heat.

This translation does not replace the portuguese version.

GLYCEROL

- $C_3H_5(OH)_3$; 92,09 [*56-81-5*]
- It contains, at least, 98.0 % and the maximum of 101.0 % of $C_3H_5(OH)_3$, in relation to the anhydrous substance.

CHEMICAL NAME
- 1,2,3-Propanotriol.

DESCRIPTION
- **Physical characteristics.** Syrupy, colorless or almost colorless, clear, hygroscopic liquid.
- **Solubility.** Mixable with water and ethanol, practically insoluble in benzene, chloroform, petroleum ether, grease oil and essential oils.

Physical-chemical constants.
- *Relative density* **(5.2.5) FB 5.** 1.25 to 1.26.

IDENTIFICATION
- Mix 1 mL of the sample and 0.5 mL of nitric acid. Add 0.5 mL of potassium dichromate at 10.6% (p/v). At the contact surface, observe the formation of a blue ring that, for 10 minutes, does not spread in the lower layer.

PURITY TESTS
- **Solution aspect.** Dilute 25 g of the sample for 50 mL of water free from carbon dioxide. The solution is clear **(5.2.25) FB 5**. Dilute 10 mL of the solution obtained for 25 mL with water. The solution is colorless **(5.2.12) FB 5**.
- **Chlorine compound.** In a rounded bottom balloon adapted to the condenser, add 5 g of the sample and 15 mL of morpholine. Heat up smoothly, under reflux, for 3 hours. Wash the condenser with 10 mL of water. Collect the washing water in the balloon. Transfer to the Nessler tube. Acidify with nitric acid SR, add 0.5 mL of silver nitrate 0.5 *M* and dilute to 50 mL with water. Stir it up. Prepare the standard in the Nessler tube, using 15 mL of morpholine, 10 mL of water and 0.2 mL of hydrochloric acid 0.02 *M*. Proceed according to what was described for the sample preparation from "Acidify…". Any turbidity developed in the sample preparation is not more intense that the one obtained with the standard preparation. A maximum of 0.003% (30 ppm).
- **Acrolein, glucose and ammoniacal compounds.** Mix 5 mL of the sample and 5 mL of potassium hydroxide at 10% (p/v). Heat up at 60 °C for 5 minutes. Ammonia steams do not detach. The color yellow does not develop.
- **Other reducing substances.** Mix 5 mL of sample with 5 mL of ammonium hydroxide at 10% (p/v) and heat up at 60 °C for 5 minutes. Add, quickly, 0.5 mL of silver nitrate 0.1 *M*, keeping the tip of the pipette above the tube, making the solution fall directly over the solution without touching the tube's walls. Stir and keep in a dark place for 5 minutes. The solution does not darken.
- **Fatty acids and esthers.** Mix 50 g of the sample with 100 mL of recently boiled hot water. Add 1 mL of phenolphthalein SI and neutralize with sulphuric acid 0.1 *M*. Add 15 mL of sodium hydroxide 0.2 *M*. Heat up under reflux, for 5 minutes, cool down and titrate with sulphuric acid 0.1 *M* SV. Carry out a white trial using 140 mL of recently boiled water. The difference between titrations is not bigger than 1.6 mL.

This translation does not replace the portuguese version.

- **Sucrose.** Add to 4 mL of the sample 6 mL of sulphuric acid 0.5 *M*. Heat up for 1 minute, cool down and neutralize with sodium hydroxide SR, using litmus paper. Add 5 mL of alkaline cupric tartrate SR and boil for 1 minute. There is no formation of orange-red precipitate.
- **Arsenic (5.3.2.5) FB 5.** Proceed according to what was described in *Visual method*. A maximum of 0.00015% (1,5 ppm).
- **Chlorides.** To 10 mL of sample solution at 10% (p/v), add 0.25 mL of nitric acid SR and 0.5 mL of silver nitrate 0.1 *M*. Stir. There is no turbidity.
- **Heavy metals (5.3.2.3) FB 5.** Use the *Method I*. Mix 4 g of the sample with 2 mL of hydrochloric acid 0.1 *M* and dilute with water to 25 mL. A maximum of 0.0005% (5 ppm).
- **Sulfates.** To 10 mL of sample solution at 10 % (p/v), add three drops of hydrochloric acid SR and five drops of barium chloride SR. There is no turbidity.
- **Water (5.2.20.1) FB 5.** Determine in 1 g of the sample. A maximum of 2.0%.
- **Sulphated ashes (5.2.10) FB 5.** Determine in 5 g of the sample. A maximum of 0.01%.

DOSAGE

- Weigh exactly about 0.1 g of the sample, transfer to 250 mL Erlenmeyer and dissolve in 45 mL of water. Add 25 mL of sulphuric acid 0,1 *M* mixture and sodium periodate at 2.14% (p/v) (1:20) and let it rest for 15 minutes, away from the light. Add 5 mL of ethylene glycol at 50% (p/v) and let it rest for 20 minutes, away from the light. Titrate with sodium hydroxide 0.1 *M* SV using 0.5 mL of phenolphthalein SI. Carry out a white trial and do the necessary corrections. Each mL of sodium hydroxide 0.1 *M* SV is equivalent to 9.210 mg of C3H5(OH)3.

PACKAGING AND STORAGE

- In perfectly closed recipients.

This translation does not replace the portuguese version.

INERT GLOBULES

- The inert globules are prepared from sucrose or a mixture of lactose and sucrose.

DESCRIPTION

- **Physical characteristics.** They are homogenous and regular spheres. They are classified numerically according to their weight. They are white, odorless and have a sweet flavor.
- The number 3, 5 and 7 globules display, respectively, an average weight of 30 mg, 50 mg and 70 mg (weight variation limit of ± 10%).
- **Solubility.** Soluble in water and insoluble in ethanol.

IDENTIFICATION

A. Dissolve 10 g of inert globules in purified water and complete the volume to 100 mL. The solution is clear **(5.2.25) FB 5** and colorless **(5.2.12) FB 5**.

B. At 3 mL of the solution described in test **A**. of *Identification*, add 3 mL of alkaline cupric tartrate SR. Boil it. Observe the formation of an orange precipitate.

C. At 3 mL of the solution described in test **A.** of *Identification*, add 3 mL of Tollens reagent. Boil it. A black precipitate (lactose) develops.

D. At 5 mL of hydrochloric acid, add some indolil acetic acid crystals and five drops of the solution described in test **A.** of *Identification*. Stir it up. Let it rest. The color violet develops (sucrose).

E. At 4 mL of the solution described in test **A.** of *Identification*, add 6 mL of sulphuric acid 0.5 *M*. Heat up for a minute, cool it down and neutralize on litmus paper with sodium hydroxide SR. Add 5 mL of alkaline cupric tartrate SR and boil it for a minute. It must produce a brick-red precipitate.

UNBUNDLING TEST

- In a metallic or perforated plastic basket, introduce the globules and dip them about 15 times per minute in a beaker with distilled water. In these conditions, the globules' unbundling time must be about 10 minutes. Dip the basket in water for two seconds and remove it for two seconds. Repeat this operation for 10 minutes, by then the globules must be totally unbundled.

PURITY TESTS

- **pH (5.2.19) FB 5.** From 5.0 to 7.0. Determine using the solution prepared be adding 10 g of inert globules to 100 mL of purified water.

PACKAGING AND STORAGE

- In a very well closed recipient.

This translation does not replace the portuguese version.

GLONOINUM

- $C_3H_5(ONO_2)_3$; 227,10 [*55-63-0*]
- It contains, at least, 81% and a maximum of 121% glycerin tri-nitrate. Its solution at 1% (v/v) in ethanol at 90% (v/v), must contain, at least, 0.95% and a maximum of 1.05% of $C_3H_5(ONO_2)_3$.

HOMEOPATHIC SYNONYM
- Trinitrinum, Glycerillis trinitras, Glycerinum trinitricum.

CHEMICAL NAME
- 1,2,3-nitro-propanotriol, glycerin tri-nitrate, glycerol tri-nitrate, trinitroglycerine, glyceryl tri-nitrate.

DESCRIPTION
- **Chemical-physical characteristics.** Clear, viscous, dense, oily, colorless or slightly yellow liquid, with sweet and spicy flavor. Explosive when under mechanical shock or heated up. *Relative density* **(5.2.5) FB 5**: About 1.642.
- **Solubility.** Not very soluble in water, but mixable with it; soluble in ethanol, mixable with ethyl ether, ketone, glacial acetic acid and chloroform.
- **Incompatibilities.** With digitalis preparations, phenytoin, levofloxacin and with heat.

IDENTIFICATION
A. To 0.3 mL of the nitroglycerin solution at 1% (v/v) in ethanol at 90% (v/v), add 20 mg of powder zinc, 0.5 mL of the 1-naphthylamine at 1% (p/v) and 0.5 mL of sulphanilic acid. A red or orange-red color develops.

B. To 0.2 mL of the nitroglycerin solution at 1% (v/v) in ethanol at 90% (v/v), add 1 mL of sodium hydroxide at 10% (p/v). Heat up at a temperature close to 60 °C, for 10 minutes. Cool down. 0.05 mL of the solution respond to the nitrate reactions **(5.3.1.1) FB 5**.

C. Heat up in water bath 5 mL of the solution formed by the dissolution of 0.25 g of the sample in 25 mL of ethanol at 90% (v/v), with 0.5 mL of the potassium hydroxide solution at 10% (p/v) until all the ethanol evaporates. Add to a portion of the residue 1 g of potassium bisulphate and heat it up. Observe the detachment of white, dense and irritant acrolein steams.

D. Leave in contact for 1 hour, 5 mL of the solution formed by the dissolution of 0.25 g of the sample in 25 mL of ethanol at 90% (v/v) with 0.5 mL of potassium iodide solution at 10% (p/v) and 5 mL of sulphuric acid solution at 1% (p/v). Observe the detachment of iodine steams.

E. Proceed according to what was described in *Thin layer chromatography* **(5.2.17.1) FB 5**, using silica gel as a support, and toluene as the mobile phase. Apply to the plate, 10 μL of *Solution (1)*, described in *Acidity*, in *Purity TESTS*. Develop the chromatogram for a 10 cm path. Remove the plate and let it air dry. Next, nebulize the plate with a diphenylamine solution at 0.1% (p/v) in ethanol at 90% (v/v). Examine under natural light. The chromatogram displays a bluish stain with Rf close to 0.70. Other stains must not appear.

PURITY TESTS
- **Acidity.** To 5 mL of *Solution (1)*, add 0.5 mL of potassium hydroxide 0.1 *M* in ethanol at 90% (v/v) and 0.1 mL of phenolphthalein SI. Observe the development of a pinkish color.

This translation does not replace the portuguese version.

  - *Solution (1)*: dissolve 1 g of the sample, weighed with the accuracy of 1 mg, in ethanol at 90% (v/v) and complete the volume to 100 mL with the same solvent.
- **Sulfates (5.3.2.2) FB 5.** With 1.5 mL of the *Solution (1)*, described in *Acidity*, proceed according to what was described in *Limit trial for sulfates*. A maximum of 0.01% (100 ppm).

DOSAGE

- Heat in water bath for 30 minutes, stirring vigorously, a mixture of 10 g of the *Solution (1)*, described in *Acidity*, in *Purity TESTS*, with 25 mL of ethanolic potassium hydroxide at 30% (v/v). Add 1mL of phenolphthalein SI and titrate with hydrochloric acid 0.5 *M* SV, until the color red disappears. Each mL of the ethanolic potassium hydroxide 0.5 *M* SV that reacted with the nitroglycerin solution corresponds to 0.023 g of C3H5(ONO2)3. The volume of ethanolic potassium hydroxide 0.5 *M* SV that reacted is equal to the added volume minus the volume of hydrochloric acid used in titration.

PACKAGING AND STORAGE

- The nitroglycerin solution at 1% (v/v) in ethanol at 90% (v/v) must be conserved in a cool environment, away from the light, in a small recipient, made of neutral, amber glass and hermetically closed. One should not use a recipient with a grinded lid due to the possibility of explosion caused by the friction of the lid and the recipient's entrance, the evaporation must also be avoided and one should be as careful as possible when manipulating the recipient, avoiding stirring it up. Keep, preferentially, at the temperature of 15 °C.

DERIVED FORMS

- **Starting point.** Nitroglycerin solution at 1% (p/v) in ethanol at 90% (v/v).
- **Inert ingredient.** Use ethanol at 90% (v/v) until 3 CH or 6 DH and for the other ones, follow the general preparation rule for derived pharmaceutical forms.
- **Method.** *Hahnemannian method (11.1), Korsakovian method (11.2), Continuous flow method* **(11.3)**.
- **Dispensation.** From 3 CH or 6 DH, follow general dispensation rule.
- **Packaging and storage.** In a neutral, amber glass environment, very well closed and away from the light and the heat.

This translation does not replace the portuguese version.

GUAIACUM OFFICINALE

- *Guaiacum officinale* (L.) – ZYGOPHYLLACEAE

HOMEOPATHIC SYNONYM
- Guaiacum sanctum, Guaiacum.

PART USED
- Resin.

PLANT DESCRIPTION
- *Guaiacum officinale* L. is a tree that may reach up to 10 m of height, with a brown and resinous stem. The branches are woody and they display leaves made up of two to three pairs of leaflets and with 3 to 5 cm of length, in the color green and with an oval pointy shape. The blue flowers are displayed in terminal spike. The fruit is an oval dark brown capsule, about 2 cm long.

DRUG DESCRIPTION
- The drug is made up of the resin obtained from the wood of *Guaiacum officinale* L. It is displayed as a mass or irregular rounded or ovoid fragments, or translucent blades with a greenish-grey surface. If broken, the drug has a light glassy fracture, whose color varies between greenish-yellow and red-brown. Usually, the drug is covered by a dark green powder. When transformed into powder, it obtains a grey color. When exposed to the light, it obtains an emerald green color. It has a characteristic aromatic smell that reminds of benjoim and vanilla, accentuated by the heat. It does not have a very intense taste in the beginning, but it becomes acre and spicy gradually.
- The resin casts at 85 °C with the detachment of a characteristic accentuated odor. It is insoluble in water, soluble in ethanol, petroleum ether and chloroform.

DRUG IDENTIFICATION

A. In order to determine the insoluble matter in ethanol, prepare the *Solution (1)* described below. The *Solution (1)* must be display more than 10% of the insoluble matter in relation to the quantity of drug (p/p).
  – *Solution (1)*: dissolve 1 g of resin in 10 mL of ethanol. Filter.

B. The *Solution (1)*, described in test **A.** of *Drug identification*, complies with the chromatographic analysis indicated for the characterization of the mother tincture. Proceed according to what was described in test **J.** of *Mother tincture identification*.

C. The *Solution (1)*, described in test **A.** of *Drug identification*, respond to the tests **A.** and **B.** of *Mother tincture identification*.

PURITY TESTS OF THE DRUG
- **Colophony determination.** Stir 1 g of powder resin with 5 mL of petroleum ether (boiling temperature between 50 °C and 60 °C), for 5 minutes. Filter. The filtered material must be colorless. Stir up the filtered material with the equal quantity of copper acetate solution at 1% (p/v). The color green must not appear.
- **Sulfated ashes (5.2.10) FB 5.** Determine in 1 g of resin. A maximum of 2%.

This translation does not replace the portuguese version.

MOTHER TINCTURE PREPARATION

- Proceed according to what was described in *Preparation of mother tincture from dry plants* **(10.1.1)**. The mother tincture is prepared from the dry resin of *Guaiacum officinale* L., through maceration with ethanol at 90% (v/v), according to the general technique of mother tincture preparation.

MOTHER TINCTURE IDENTIFICATION

A. A. Prepare the *Solution (2)* described below. Observe the intense milk and permanent turbidity.
  – *Solution (2)*: in 1 mL of mother tincture, add 5 mL of purified water.

B. To the *Solution (2)*, described in the test **A.** of *Mother tincture identification*, add two drops of the mixture formed right before use by equal parts of the ferric chloride solution at 1% (p/v) and potassium ferrocyanide 1% (p/v). An intense indigo color develops.

C. To 1 mL of the mother tincture, add 1 mL of ethanol. Next, add one drop of the ferric chloride solution at 1% (p/v). An intense blue color develops and turns, successively, into green and, then, yellow, by adding excessive reagent.

D. To 2 mL of the mother tincture, add one drop of the Tollens reagent. An intense blue color develops at cold. When heated up in boiling water bath for 2 minutes, the color turns into a dark green with the formation of precipitate.

E. To 2 mL of the mother tincture, add 1 mL of purified water and 3 mL of alkaline cupric tartrate SR. A green color develops at cold, tuning into yellow green when heated up in boiling water bath for 2 minutes.

F. To 1 mL of the mother tincture, add five drops of sodium hydroxide solution at 10% (p/v). A red-brown color develops.

G. To 1 mL of mother tincture, add 1 mL of ethanol and five drops of copper sulfate solution at 1% (p/v). A blue color develops and intensifies while adding one drop of the ammonium thiocianate solution at 1% (p/v).

H. To 2 mL of the mother tincture, add five drops of silver nitrate solution at 1% (p/v). Heat up in boiling water bath for 1 minute. The color blue develops and, when it is heated up for another minute, it originates a dark grey precipitate.

I. To 2 mL of the mother tincture, add 2 mL of purified water. Extract the mixture with 5 mL of chloroform. Separate the chloroformic phase by transferring it to a porcelain capsule. Evaporate until it dries. Treat the residue obtained with this procedure with drops of sulphuric acid. The color violet develops.

J. Proceed according to what was described in *Thin layer chromatography* **(5.2.17.1) FB 5**, using G silica gel as a support and a mixture of methylene chloride and isopropyl alcohol (30:20) as the mobile phase. Apply, separately, to the plate, 10 μL of the mother tincture and 10 μL of the *Standard solution* prepared recently, described below.
  – *Standard solution*: dissolve 10 mg of vanilin in about 10 mL of ethanol.

- Carry the chromatogram for a 10 cm path. Remove the plate, let it air dry. Examine under visible light. The chromatogram obtained with the mother tincture usually displays three blue stains with Rfs close to 0.15, 0.20 and 0.65. Examine it under ultraviolet light (365 nm). Nebulize the plate with phloroglucinol solution at 1% (p/v) in ethanol, with drops of hydrochloric acid. Examine it under visible light. The chromatogram obtained with the *Standard solution* displays orange stains with Rf close to 0.60, while the one which corresponds to the mother tincture displays an brown yellow stain with Rf close to 0.10, another yellow stain with Rf close to 0.20, another blue one with Rf close to 0.45, another violet one, with Rf close to 0.50 and the last one, orange, with Rf close to 0.60.

This translation does not replace the portuguese version.

PURITY TESTS

- **Ethanol title.** Must be between 85 and 95% (v/v).
- **Dry residue.** Must be equal or superior to 7.0% (p/v).

PACKAGING AND STORAGE

- In a neutral, amber glass recipient, hermetically closed and away from the light and the heat.

DERIVED FORMS

- **Starting point.** Mother tincture.
- **Inert ingredient.** From 1 CH until 3 CH or 1 DH until 6 DH, using the same alcoholic content as the mother tincture. For the other dynamizations, follow the general preparation rule for the derived pharmaceutical forms.
- **Method.** *Hahnemannian method (11.1), Korsakovian method (11.2), Continuous flow method* **(11.3)**.
- **Dispensation.** From1 DH or 1 CH.
- **Packaging and storage.** In a neutral, amber glass recipient, very well closed and away from the light and the heat.

This translation does not replace the portuguese version.

HYDRASTIS CANADENSIS

- *Hydrastis canadensis* (L.) – RANUNCULACEAE

HOMEOPATHIC SYNONYM
- Hydrastis, Warneria canadenses, Hidraste.

PART USED
- The vegetal drug consists of desiccated and fragmented rhizomes and roots.

MACROSCOPIC DESCRIPTION
- The rhizome grows horizontally or obliquely and sustain several small branches, besides adventitious roots. The rhizome is cylindrical, tortuous, dilated many times, wrinkled lengthwise, about 1 to 6 cm long and with 0.2 to 1.0 of diameter; outside it is yellow-brown or grey-brown and inside it is light yellow in the center and greenish yellow close to the borders. Outside, it is marked by several sort of circular scars, derived from the fallen stems, and other smaller ones, from the fallen sprouts and roots. The roots, originated in the ventral and lateral surfaces, are numerous, stringy, with 0.1 cm of diameter and 3.5 cm of length, curved, twisted, fragile, easily separable and detachable, with a color that is similar to the rhizome.

MICROSCOPIC DESCRIPTION
- The rhizome displays, from the borders to the center, the following tissues: yellow-brown suber fragments, compounds of polygonal cells in frontal view, with thin and lignified walls; fragments, transversally, with frequent irregular mass of brown granular material, that may darken the suber's cells on the outside. Cortical parenchyma with about 25 layers of polygonal rounded cells, with thin walls, transversally and long lengthwise, containing starch grains and yellowish masses. The starch grains are, mostly simple, but they may also contain two, three or four components. This parenchyma's external region cells have thick walls with the appearance of a collenchyma. Next, there is a circle of twelve to twenty collateral vascular beams, separated by large rows of orange yellowish to greenish yellow parenchymatic cells. The xylem is made up of small vessel elements, of the following types: helical, pointed and reticulated (the rarest), with perforation plate in oblique terminal walls. The central part is occupied by a wide medullar parenchyma. The transversal cut of the root shows an epidermis made up of a single layer of yellowish brown cells, with suberified external walls. These, in frontal view, are longer and more irregular than the rhizome one, some originated trichomes. The cortical parenchyma, of thick wall cells, contains starch. The endoderm has cells with slightly lignified walls; in the young roots, in tangential section, the cells show to be long, with thin walls and markedly sinuous. The vascular system displays from two to six xylem's gables, alternated with the phloem. The medulla consists of a small central area with not very evident parenchymatic cells.

MICROSCOPIC DESCRIPTION OF THE POWDER
- The powder complies with all the requirements established for the species, except for the microscopic characters. The characteristics are: yellowish to greenish-yellow color; abundant spherical starch grains, isolated or gathered in groups of two, three or four components; parenchyma fragments containing starch grains; few fragments of yellowish-brown suber, made up of polygonal cells in frontal view, and, in transversal view, showing irregular masses

This translation does not replace the portuguese version.

of dark brown granular substance over the outside of the suber; fragments of vascular tissue, containing vessel elements with aerial ratings, some with helical thickening, not frequent xylem fibers, from 200 to 300 μm of length, of thin walls and simple pores; occasional fragments of the endoderm; several spherical masses to ovoids, of granular orange-brown substance, spread throughout the whole powder. The powder does not have neither calcium oxalate crystals nor sclerified cells (sclereids).

MOTHER TINCTURE PREPARATION

- Proceed according to what was described in the *Preparation of the plant origin mother tincture*
- **(10.1)**. The mother tincture of *Hydrastis canadensis* is prepared through maceration or percolation, so that the alcohol content, both throughout and at the end of the extraction, is 65% (v/v), according to the general technique of mother tincture preparation.

MOTHER TINCTURE CHARACTERISTICS

- Yellowish brown liquid with characteristic odor and bitter taste.

IDENTIFICATION

A. Evaporate 2 mL of the mother tincture until it dries in water bath. To the residue, add six drops of diluted hydrochloric acid at 10% (p/v) and three drops of mercury potassium iodide SR. Observe the formation of a yellow precipitate.

B. To 1 mL of sulphuric acid, add two drops of T-chloramine solution at 10% (p/v). After cooling it down, add 1 mL of the mother tincture. Observe the development of a dark red color.

C. Evaporate 10 mL of the mother tincture in water bath. To the residue, add 5 mL of chloroform. Leave in contact for 30 minutes and filter. Evaporate the filtered material in water bath. To the residue, add 1 mL of sulphuric acid and some ammonium molybdate crystals. Observe the development of a blue color (hydrastine).

D. Acidify 0.5 mL of mother tincture with diluted sulphuric acid at 5% (p/v). Stir with 10 mL of ethyl ether. Observe under ultraviolet light (365 nm), the ethereal phase displays blue fluorescence.

E. Proceed according to what was described in *Thin layer chromatography* **(5.2.17.1) FB 5**, using silica gel as a support, and ethanol at 60% (v/v) as the mobile phase. Apply separately to the plate, 20 μL of the mother tincture and 20 μL of each one of the prepared recently reference solution, as described below

  – *Reference solution A*: transfer 10 mg of hydrastin hydrochloride to a 10 mL volumetric balloon, dilute and complete the volume with ethanol at 60% (v/v).
  – *Reference solution B*: transfer 10 mg of berberine hydrochloride to a 100 mL volumetric balloon, dilute and complete the volume with ethanol at 60% (v/v).

- Develop the chromatogram for a 10 cm path. Remove the plate, let it air dry. Examine under daylight. The chromatogram obtained with the mother tincture displays a yellow stain with Rf close to 0.10. Examine under ultraviolet light (365 nm). The chromatogram obtained with the sample displays fluorescent yellow stains with Rf close to 0.85. Nebulize the chromatoplate with potassium bismuth iodide SR2. Examine under daylight. The chromatogram obtained with the reference solutions displays orange stains and Rf close to 0.10 (berberin) and 0.45 (hydrastin). The chromatogram obtained with the mother tincture displays two orange stains of Rfs close to 0.10 (berberin) and 0.45 (hydrastin).

This translation does not replace the portuguese version.

PURITY TESTS

- **Ethanol title.** Must be between 60% and 70% (v/v).
- **Dry residue.** Must be equal or superior to 1,2% (p/v).

PACKAGING AND STORAGE

- In a neutral and amber glass recipient, very well closed and away from the light and heat.

DERIVED FORMS

- **Starting point.** Mother tincture
- **Inert ingredient.** From 1 CH until 3 CH or 1 DH until 6 DH, using the same alcoholic content as the mother tincture. For the other dynamization, follow the general preparation rule for derived pharmaceutical forms.
- **Method.** *Hahnemannian method (11.1), Korsakovian method (11.2), Continuous flow method* **(11.3)**.
- **Dispensation.** From the mother tincture, following the main dispensation rule.
- **Packaging and storage.** In a neutral and amber glass recipient, very well closed and away from the light and heat.

This translation does not replace the portuguese version.

HYOSCYAMUS NIGER

- *Hyoscyamus niger* (L.) – SOLANACEAE

HOMEOPATHIC SYNONYM
- Hyoscyamus, Hyoscyamus agrestis, Hyoscyamus lethalis.

PART USED
- Whole flowered dry plant.

PLANT DESCRIPTION
- *Hyoscyamus niger* L. is a herbaceous biannual, deciduous plant with spindle-shaped root, with nauseous odor, and 30 to 60 cm tall. The stem is cylindrical, covered by long piles and a small black gland on the tip. The leaves are light green. The limb, that may reach up to 25 cm, is oval and spear-shaped to triangular-oval, thin and triangular. The sessile leaves are heart-shaped in the base and the petiolated leaves are elliptical, both display an acute apex. The border of the leaves is irregularly dented. They are intensely pubescent and viscous on the dorsal side and the ventral side and, particularly, along the medium nerve and the main nerves, being the medium nerve very large and developed. The secondary nerves form an accentuated angle with the medium nerve. The flowers are intensely pubescent forming compact masses, the flowers are grouped and develop in axilla of big bracts. They display a gamosepalous calyx, they are strongly campanulate containing five triangular lobes. They are yellow and not shiny, being markedly reticulated with purple veins, showing themselves in unilateral inflorescence, like a spike. The fruit is a bilocular pixide that ends up in an unceolated persistent calyx.

DRUG DESCRIPTION
- *Hyoscyamus niger* L. characteristically displays heterogeneous and assymetrical mesophilic. The epidermises are covered by a flat cuticle. They display non-glandular piles of the conic uniserial type, most of the times with four to ten cells. The glandular piles display uniserial pedicel with one to four cells covered by a perceived unicellular or bicellular gland or septated gland. Glandular pile of uniserial pedicel and key-shaped glandular also occur in the epidermis. The stomata are of the anisocytic type.
- The palisade parenchyma is made up of a single cellular layer. This parenchyma's cells correspond to half of the mesophilic thickness. The lacunous parenchyma is usually made up of four to six arm-shaped cellular cells, the first layer is made up of lacunous parenchyma located right below the palisade parenchyma and characterized by displaying prismatic crystals or calcium oxalate drusen.
- The vascular beams, especially in the medium nerves, are the bicollateral type.
- The stem displays eustelic structure with the bicollateral vascular beams placed in circles and separated by narrow medullar beams. The cortical region displays cells that contain calcium oxalate prismatic crystals as well as the medullar parenchyma region.
- The epidermis displays tector and glandular piles which are similar to the ones on the leaves.

MOTHER TINCTURE PREPARATION
- Proceed according to what was described in *Preparation of the plant origin mother tincture* **(10.1)**. The mother tincture of *Hyoscyamus niger*. is prepared by maceration or percolation,

so that the alcohol content, both throughout and at the end of the extraction, is 45% (v/v), according to the general technique of mother tincture preparation.

MOTHER TINCTURE CHARACTERISTICS

- Dark greenish brown liquid, with nauseous odor and bitter and nauseous flavor.

IDENTIFICATION

A. Acidify 10 mL of the mother tincture with hydrochloric acid at 5% (v/v). Extract with 10 mL of ethyl ether. Discharge the ethereal phase and use the aqueous phase that must be made alkaline with the sufficient amount of concentrated ammonium hydroxide. Extract with 15 mL of ethyl ether, separate the ethereal phase and take it to evaporation in boiling water bath until it dries. To the residue obtained this way, add 0.5 mL of steamy nitric acid and evaporate, in water bath, until it dries. Add 5 mL of ketone, followed by the addition, drop by drop, of potassium hydroxide solution at 3% (p/v) in ethanol at 96% (v/v). An intense violet color develops.

B. Put 10 mL of the mother tincture to evaporate in boiling water bath. Treat the residue obtained with 10 mL of purified water, filter and extract the filtered material with 10 mL of chloroform, separate and evaporate the chloroformic extract in boiling water bath. Treat the residue formed with 10 mL of purified water previously heated up and add to the solution formed this way, 1 mL of concentrated ammonium hydroxide. Examine under ultraviolet light (365 nm). The mixture displays a blue fluorescence.

C. Evaporate 1 mL of the mother tincture in boiling water bath. Treat the residue with some drops of hydrochloric acid at 10% (v/v). To the solution, add some drops of potassium bismuth iodide SR2. Observe the formation of an orange precipitate.

D. Proceed according to what was described in test **C**. of *Identification*, substituting the potassium bismuth iodide SR2 by the mercury potassium iodide SR. Observe the formation of a white precipitate.

E. Proceed according to what was described in *Thin layer chromatography* **(5.2.17.1) FB 5**, using silica gel as a support, and a mixture of ketone, purified water and ammonium hydroxide (90:7:3), as the mobile phase. Apply separately to the plate, 10 μL of one of the standard solutions described below, and 20 μL of the mother tincture.

  – *Standard solution of hyoscyamine sulfate – scopolamine hydrobromide*: transfer 20 mg of hyoscyamine sulfate to the 10 mL volumetric balloon and complete the volume with methanol. In parallel, transfer 10 mg of scopolamine hydrobromide to the 10 mL volumetric balloon, dilute and complete the volume with methanol. Prepare a mixture of 5 mL of scopolamine hydrobromide solution and 5 mL of hyoscyamine sulfate solution.

  – *Standard solution of atropine sulfate*: transfer 10 mg of atropine sulfate to the 10 mL volumetric balloon, dilute and complete the volume with methanol.

- Develop the chromatogram in a 10 cm path. Remove the plate and let it dry between 100 °C and 105 °C, until the total elimination of the solvent mixture. Let it cool down. Nebulize with potassium bismuth iodide SR2. Observe the appearance of orange or brown stains on a yellow background, the Rf values correspond to the mother tincture similar to the standards used.

PURITY TESTS

- **Ethanol title.** Must be between 40% and 50% (v/v).
- **Dry residue.** Must be equal or superior to 1,0% (p/v).

This translation does not replace the portuguese version.

PACKAGING AND STORAGE

- In a neutral and amber glass recipient, very well closed and away from the light and heat.

DERIVED FORMS

- **Starting point.** Mother tincture
- **Inert ingredient.** From 1 CH until 3 CH or 1 DH until 6 DH, using the same alcohol content as the mother tincture. For the other dynamizations, follow the general preparation rule for derived pharmaceutical forms.
- **Method.** Hahnemannian method (11.1), Korsakovian method (11.2), Continuous flow method **(11.3)**.
- **Dispensation.** From 1 CH or 2 DH, following the general dispensation rule.
- **Packaging and storage.** In a neutral and amber glass recipient, very well closed and away from the light and heat.

This translation does not replace the portuguese version.

HYPERICUM PERFORATUM

- *Hypericum perforatum* (L.) – HYPERICACEAE

HOMEOPATHIC SYNONYMY
- Hypericum, Hipérico, Fuga daemonum, Herba solis, Hypericum pseudo perforatum, Hypericum officinale, H. virginicum, H. vulgare, H. umbelicalis.

PART EMPLOYED
- Entirely bloomed plant

PLANT DESCRIPTION
- *Hypericum perforatum* L. is a perennial species, with an erect stem that reaches about 30 cm. Opposite, oblong or elliptical, whole, sessile and glabrous leaves, with dark spot near the edges and translucent stains through the whole limb due to the schizogenic essence bags, when observed by transparency; flowers on corymbiform, hermaphroditic, pentamerous cymes, or of persistent cup; five bright yellow petals, with glands on the edge; ovary comprised of 3 to 5 carpel, with 3 stilettos capsular dehiscent fruit with 3 valves (on the sepals and petals are noted dark spots on the leaves edges as well). Aromatic and persistent odor; bitter and astringent flavor.

PREPARATION OF MOTHER TINCTURE
- Proceed as described on *Preparation of mother tincture of vegetable origin* **(10.1)**. The *Hypericum perforatum* mother tincture is prepared by maceration or percolation, so the alcohol level during and at the end of the extraction is of 65% (v/v), according to the preparation of mother tincture's general technique.

MOTHER TINCTURE FEATURES
- Dark red liquid of faint odor and slightly bitter flavor.

IDENTIFICATION

A. Add a few drops of ferric chloride solution at 10% (p/v) to 2mL of mother tincture. Dark green color is developed.

B. Add 2 mL of purified water and 2 mL of ethyl ether to 2 mL of mother tincture, with a slight shake. Examine under ultraviolet light (365 nm). The ethereal phase presents an intense red fluorescence (hypericin).

C. Add 1 mL of sulfuric acid to 2 mL of the ethereal phase. Examine under ultraviolet light (365 nm). Green-yellow fluorescence is observed.

D. Proceed as described in *Chromatography on slender layer* **(5.2.17.1) FB 5**, using G silica gel, as support, and mixture of 1-butanol, glacial acetic acid and water (4:1:1), as mobile phase. Apply to the plate 20 mL of mother tincture. Develop the chromatogram through a length of 10 cm. Remove the plate, leave it to dry. Examine under ultraviolet light (365 nm). The chromatogram presents 2 dark brown stains with Rfs close to 0.60 and 0.80, 1 with intense red fluorescence with Rf close to 0.85, 1 with yellowish brown fluorescence with Rf close to 0.90 and 1 with red fluorescence, with Rf close to 0.95. Nebulize the chromatographic plate with aluminum chloride solution at 5% (p/v) on ethanol at 90% (v/v). Examine under ultraviolet light (365 nm). The chromatogram presents a series of yellow fluorescent stains and of Rfs close to 0.45, 0.60, 0.80 and 0.90.

This translation does not replace the portuguese version.

- Develop a second chromatogram in the same conditions above. Nebulize the chromatographic plate with SR vanillin, heat it between 100ºC and 105ºC and examine under day light. The chromatogram presents dark gray stain with Rf close to 0.30, several dark brown stains with Rfs between 0.50 and 0.60, a pink stain with Rf close to 0.80, one with violet gray color and Rf close to 0.85 and one violet with Rf close to 0.98.

PURITY TESTS
- **Title in ethanol.** Must be between 60% and 70% (v/v).
- **Dry residue.** Must be above 1.3% (p/v).

PACKAGING AND STORAGE
- In an amber, neutral glass container, tightly closed, away from sunlight and heat.

DERIVATIVE FORM
- **Starting point.** Mother tincture.
- **Inert input.** From 1 CH to 3 CH or 1 DH to 6 DH use the mother tincture same alcohol level. For others dilutions, follow the general rule of derivative pharmaceutical forms preparation.
- **Method.** *Hahnemannian Method* **(11.1)**, *Korsakovian Method* **(11.2)**, *Continuous Flow Method* **(11.3).**
- **Disposal.** From the mother tincture, following general rule of disposal.
- **Packaging and storage.** In an amber, neutral glass container, tightly closed, away from sunlight and heat.

This translation does not replace the portuguese version.

IGNATIA AMARA

- *Strychnos ignatii* Bergius – LOGANIACEAE

HOMEOPATHIC SYNONYMY
- Ignatia, Strychnos ignatii, Faba indica, Faba Santi Ignatii.

PART EMPLOYED
- Dry seeds.

PLANT DESCRIPTION
- *Strychnos ignatii* Bergius is a tall, climbing and ligneous bush, with opposite, no stipules, ovate and glabrous leaves and white tubular flowers. It's fruit is a big piriform berry, wrapped in a somewhat dry peel that envelops a meaty pulp of greenish color and bitter flavor, with up to 24 seeds of the size of almonds, more frequently, though, 10 or 12.

DRUG DESCRIPTION
- The seeds are hard, heavy, ovate with obtuse angles, with length of 20 mm to 30 mm and approximately 15 mm of width and thickness. Has an exterior of grayish or reddish-black color, almost smooth, with little to no hair. The semifinal cover is thin and can be peeled off by friction. The umbilicus is quite evident and has a circular format on the basis of the seed. The embryo presents foliar cotyledons and the radiculo-stem axis is reduced. The endosperm corneous and translucent.

PREPARATION OF MOTHER TINCTURE
- Proceed as described on *Preparation of mother tincture of vegetable origin* **(10.1)**. The *Ignatia amara* mother tincture is prepared by maceration or percolation, so the alcohol level during and at the end of the extraction is of 65% (v/v), according to the preparation of mother tincture's general technique.

MOTHER TINCTURE FEATURES
- Amber-yellow liquid of faint odor and bitter flavor.

IDENTIFICATION
A. Add 1 drop of sulfuric acid at 5% (p/v) to 5 drops of mother tincture. Boil until it dries. It develops a violet color.
B. Add a few drops of ferric chloride solution at 10% (p/v) to 1 mL of mother tincture. A green color is developed.
C. To 1 mL of mother tincture add a few drops of the reagent prepared at the moment of use and formed by equal parts of ferric chloride solution at 1% (p/v) and potassium ferricyanide at 1% (p/v). An intense blue color is developed.
D. Evaporate 2 drops of mother tincture. Add 2 drops of concentrated nitric acid to the residue. An orange color is developed.
E. Proceed as described in *Chromatography on slender layer* **(5.2.17.1) FB 5**, using G silica gel, as support, and use the inferior part of the solvents mix formed by chloroform, methanol and concentrated ammonium hydroxide (95:5:1) as mobile phase. Separately, apply to the plate 10 mL of mother tincture and the same amount of the *Strychnine Standard Solution* and the *Brucine Standard Solution*, recently separated, described below.

This translation does not replace the portuguese version.

  - *Strychnine Standard Solution*: dissolve 10 mg of strychnine in an enough ethanol amount at 96% (v/v). Complete the volume to 10 mL using the same solvent.
  - *Brucine Standard Solution:* dissolve 10 mg of brucine in an enough ethanol amount at 96% (v/v). Complete the volume to 10 mL using the same solvent.
- Develop the chromatogram through a 10 cm length. Remove the plate, let it dry and, if necessary, heat it to a temperature between 105ºC and 110ºC for 15 minutes for total elimination of the solvents mix. After cooled, nebulize the plate with iodoplatinate reagent. Examine under natural light. A violet stain is observed, with Rf close to 0.70, equivalent to the strychnine, and a blue one, with Rfs close to 0.70 and 0.65, with the colors equivalent to the strychnine and the brucine.
- Develop a second chromatogram in the same conditions as the previous one, except for the use of solvents mixture formed by toluene, ethyl acetate and diethylamine (7:2:1) as mobile phase. Perform the drying of the plate, as described before. Examine under ultraviolet light (254 nm). An intense blue stain is observed at the starting point and two other blue ones of less intensity, respectively equivalent to the strychnine and brucine patterns. On a second step, nebulize the plate with SR2 potassium iodobismuthate. In the area of Rf 0.25 to 0.55 two orange-brown stains are observed, equivalent to the strychnine and brucine patterns, but on the zone correspondent to the mother tincture 3 additional stains are observed, less intense and smaller, equivalent, respectively, to α-colubrine, β-colubrine and the pseudo-strychnine, all of an orange-brown color.

PURITY TESTS
- **Title in ethanol.** Must be between 60% e 70% (v/v).
- **Dry residue.** Must be greater than or equal to1% (p/v).

PACKAGING AND STORAGE
- In an amber, neutral glass container, tightly closed, away from sunlight and heat.

DERIVATIVE FORM
- **Starting point.** Mother tincture.
- **Inert input.** From 1 CH to 3 CH or 1 DH to 6 DH use the mother tincture same alcohol level. For others dilutions, follow the general rule of derivative pharmaceutical forms preparation.
- **Method.** *Hahnemannian Method* **(11.1)**, *Korsakovian Method* **(11.2)**, *Continuous Flow Method* **(11.3).**
- **Disposal.** From 1 CH or 2 DH, following general rule of disposal.
- **Packaging and storage.** In an amber, neutral glass container, tightly closed, away from sunlight and heat.

This translation does not replace the portuguese version.

IODIUM

- I_2; 253,81 [*7553-56-2*]
- Contains a minimal of 99.5 % and a maximum of 100.5% of I.

HOMEOPATHIC SYNONYMY
- Iodo, Iodum, Iodum purum, Iodium metallicum, Iodum metallicum.

CHEMICAL NAME
- Iodine.

DESCRIPTION
- **Physical aspects.** Fine and violet crystals with a metallic glow.
- **Solubility.** Very slightly soluble in water, soluble in ethanol, slightly soluble in glycerin. Very soluble in concentrated iodide solutions.

IDENTIFICATION
- Heat a small portion of the sample in a test-tube. Violet vapors are released and condense on the tube's walls in the form of bluish crystals.
- Add SR starch to a saturated solution of the sample. A blue color is produced. Heat until discoloration. With cooling the blue coloration reappears.

DOSAGE
- Transfer exactly about 0.2 g of iodine to the Erlenmeyer flask with 1 g of potassium iodide and 2 mL of water. Add 1 mL of diluted acetic acid and, after dissolution, add 50 mL of water. Titrate with 0,1 *M* SV sodium thiosulfate, at a temperature below 15ºC, until discoloration of the dark yellow to a pale yellow. Add a few drops of SI starch and continue the titration until the blue fades away. Each mL of 0,1 *M* SV sodium thiosulfate is equivalent to 12,691 mg of I.

PACKAGING AND STORAGE
- In an amber, neutral glass container, with abraded cover, away from sunlight and heat.

DERIVATIVE FORM
- **Starting point.** Iodine (I2).
- **Inert input.** Ethanol at 96% (v/v). Considering the iodine's incompatibility with lactose and it's solubility in ethanol, in this case, the alcohol level of the inert input must be of 96%.
- **Method.** *Hahnemannian Method* **(11.1)**, *Korsakovian Method* **(11.2)**, *Continuous Flow Method* **(11.3).**
- **Disposal.** From 1 CH and 1 DH. Ethanol in the same ethanolic title of the inert input will be employed.
- **Packaging and storage.** In a colorless and neutral container, tightly closed.

This translation does not replace the portuguese version.

IPECACUANHA

- *Cephaelis ipecacuanha* (Brotero) Richard – RUBIACEAE

HOMEOPATHIC SYNONYMY
- Radix, Ipeca, Cephaelis emetica, Psychotria ipecacuanha, Ipeca officinalis.

PART EMPLOYED
- Dry root.

PLANT DESCRIPTION
- *Cephaelis ipecacuanha* (Brotero) Richard is a semi-bushy, perennial and scattered plant, with opposite leaves provided with interpetiolar stipules. The flowers are small, white, with infundibuliform corollas. The ovary is inferior bicarpelar and bilocular. The fruits are drupes with endocarp and 2 dark purple seeds. The underground portion is formed by a slender rhizome with filiform, ringed roots and smooth, slender roots. The rhizoma is arched up and continues in a short aerial and green stem, and presents sparse and opposite petiolate leaves, with whole and obovate stipules.

DRUG DESCRIPTION
- Tortuous root, simple or rarely branched, with up to 15 cm of length and 6 mm of width. Color varying from brick-red to dark brown. In it's exterior presents numerous wrinkly rings separated from each other by round grooves all around the root. Presents brief fracture on the peel and chipped wood. Smooth surface in transverse cut, with wide and thick grayish peel; ligneous and not very thick central part, evenly dense and very hard. Short and cylindrical rhizomes, usually bound to the root, with up to 2 mm of diameter, with fine longitudinal wrinkles, with medullary parenchyma occupying approximately 1/6 of the total diameter.
- The root consists of a fine layer of brown suber with 3 to 4 layers of tabular, flat, polyhedral cells, with thin walls and large phelloderm parenchymal band. The cortical parenchyma is developed by and consisted of tissue of cells filled with starch grains and of larger cells with raphides. Phelloderm and parenchymal rays cells are filled with starch grains, simple or with 2 to 8 components. Oval, round or roughly hemispheric individual grains are also rarely observed with more than 15 mm of diameter. The triplet grains often show a smaller component and the quadruplet ones, 2 smaller components. Crystal cells are present in the parenchymal tissues, each one with a beam of raphides with a length of 30 mm to 80 mm. The phloem has no fibers and is constituted of a narrower layer of cells when compared to the xylem. The xylem is dense, consisting primarily of narrow tracheids, mixed with smaller proportion of vessels, both with simple and haloed punctuations on the side walls. Rhizome presenting, on the cross section of an internode, several layers of thin walled suber. The cortex is slightly collenchymatous and the pericycle presents groups of large sclereids, clearly punctuated. A small phloem ring and large xylem ring occurs internally, circling the medullary parenchyma (pith) composed by cells with haloed and thin walled punctuations.

PREPARATION OF MOTHER TINCTURE
- Proceed as described on Preparation of mother tincture of vegetable origin **(10.1)**. The *Ipecacuanha* mother tincture is prepared by maceration or percolation, so the alcohol level during and at the end of the extraction is of 65% (v/v), according to the preparation of mother tincture's general technique.

This translation does not replace the portuguese version.

MOTHER TINCTURE FEATURES

- Reddish-brown liquid of unpleasant odor and bitter and disgustful flavor.

IDENTIFICATION

A. Add 10 mL of purified water to 1 mL of mother tincture. Shake vigorously. A formation of an abundant foam is observed.

B. Add 5 drops of ferric chloride solution at 10% (p/v) to 1 mL of mother tincture. A dark green color is developed.

C. Add to 1 mL of mother tincture 5 drops of reagent formed, in the moment of use, by mixing equal parts of ferric chloride solution at 1% (p/v) and potassium ferricyanide solution at 1% (p/v). An intense blue color is developed. Boil 2 mL of mother tincture until it evaporates. Add to the residue 5 drops of hydrochloric

D. Acid at 10% (v/v) and 3 drops of SR mercuric potassium iodide. A formation of white precipitate is observed.

E. Boil 2 mL of mother tincture until it evaporates. Add to the residue 5 drops of hydrochloric acid at 10% (v/v) and 3 drops of SR2 potassium iodobismuthate. A formation of orange precipitate is observed.

F. Shake 2 mL of mother tincture with 10 mL of ethyl ether and a few drops of concentrated ammonium hydroxide. Separate the ethereal phase and boil it until evaporates. Add to the attained residue 5 drops of sodium molybdate solution at 0.5% (p/v) in sulfuric acid. A violet color is developed, which then turns into green.

G. Proceed as described in *Chromatography on slender layer* **(5.2.17.1) FB 5**, using G silica gel, as support, and use chloroform and methanol (85:15) as mobile phase. Separately, apply to the plate 5 mL of *Sample Solution* and the *Standard Solution*, recently prepared, described below.

- *Sample Solution*: Boil 2 mL of mother tincture until it evaporates. Add to the attained residue 1 mL of concentrated ammonium hydroxide and 5 mL of chloroform. Shake vigorously and leave it to rest for 30 minutes. Filter.
- *Standard* Solution: dissolve 4,6 mg of emetine hydrochloride and 5,7 mg of cephalin hydrochloride in 20 mL of chloroform.

- Develop the chromatogram through a 10 cm length. Develop a second time with the same mobile phase. Remove the plate, let it dry. Nebulize with iodine solution at 5% (p/v) in chloroform. Dry at 60ºC for 10 minutes. Examine under natural light. The *Standard Solution* presents a citrine-yellow stain equivalent to the emetine and, lower, a light brown stain equivalent to the cephalin. Then, examine the plate under ultraviolet light (365 nm). The stain equivalent to the emetine presents intense yellow fluorescence and the one equivalent to the cephalin presents light blue fluorescence. The chromatogram attained with the chloroform extract from mother tincture presents the same stains, with the same fluorescent features.

PURITY TESTS

- **Title in ethanol.** Must be between 60% and 70% (v/v).
- **Dry residue.** Must be greater or equal to 0.9% (p/v).

PACKAGING AND STORAGE

- In an amber, neutral glass container, tightly closed, away from sunlight and heat.

DERIVATIVE FORM

- **Starting point.** Mother tincture.

This translation does not replace the portuguese version.

- **Inert input.** From 1 CH to 3 CH or 1 DH to 6 DH use the mother tincture same alcohol level. For others dilutions, follow the general rule of derivative pharmaceutical forms preparation.
- **Method.** *Hahnemannian Method* **(11.1)**, *Korsakovian Method* **(11.2)**, *Continuous Flow Method* **(11.3).**
- **Disposal.** From 1 CH to 2 DH, following general rule of disposal.
- **Packaging and storage**. In an amber, neutral glass container, tightly closed, away from sunlight and heat.

This translation does not replace the portuguese version.

KALI BICHROMICUM

- $K_2Cr_2O_7$; 294,19 [*7778-50-9*]
- Desiccated in a greenhouse at 105 °C, until constant weight, contains, at least, 99% of $K_2Cr_2O_7$.

HOMEOPATHIC SYNONYMY
- Kalium bichromicum, Kali dichromicum, Potassium bichromate.

CHEMICAL NAME
- Potassium bichromate, Potassium dichromate.

DESCRIPTION
- **Physical aspects.** Orange crystals, transparent crystals or crystal powder. Odorless, of metallic flavor, stable to air.
- **Solubility.** Soluble in water and insoluble in ethanol.
- **Incompatibilities.** Barium, lead and mercury salts, alkaloids and it's salts, and lactose.

IDENTIFICATION

A. Small amount of the sample, dampened with hydrochloric acid, in platinum loop, taken to the non enlightening zone of the Bunsen Burner's flame, gives a violet color to it.

B. The sample's aqueous solution at 5% (p/v) is acid to litmus' blue paper.

C. Prepare the *Solution (1)* described below. Add 5 drops of lead acetate aqueous solution at 1% (p/v) to 5 mL of the *Solution (1)*. A formation of yellow precipitate is observed.
- *Solution (1)*: potassium bichromate aqueous solution at 5% (p/v).

D. Add 5 drops of silver nitrate aqueous solution at 1% (p/v) to 5 mL of the *Solution (1)*, described in test **C**. of *Identification*. A formation of reddish-brown precipitate is observed.

E. Add 5 mL of purified water and 2 mL of hydrochloric acid aqueous solution at 10% (v/v) to 2 mL of the *Solution (1)*, described in test **C.** of *Identification*. Gradually add 1 mL of ethanol. A green color is developed.

PURITY TESTS
- **Aluminum and Calcium.** Dissolve 2 g of potassium bichromate in 20 mL of purified water. Alkalise with ammonium hydroxide. Add 5 drops of ammonium oxalate aqueous solution at 1% (p/v). Turbidity or precipitation should not be observed.
- **Chlorides.** Add 2 mL of nitric acid aqueous solution at 10% (v/v) and 5 drops of silver nitrate aqueous solution at 1% (p/v) to 2 mL of a potassium bichromate aqueous solution at 1% (p/v). Turbidity or precipitation should not be observed.
- **Sulphates.** Add 1 mL of barium nitrate aqueous solution at 10% (p/v) to 2 mL of a potassium bichromate aqueous solution at 1% (p/v). Turbidity or precipitation should not be observed within 3 minutes.

DOSAGE
- Dissolve 0.2 g of potassium bichromate in 25 mL of purified water, recently boiled and cooled, in a container with a lid. Add 2 g of potassium iodide and 10 mL of concentrated hydrochloric acid. Leave quiescent, in the dark, for 10 minutes. Add 200 mL of purified water recently boiled and cooled. Titrate with 0.1 *M* SV sodium thiosulfate using starch solution as indicator. Each mL of 0.1

This translation does not replace the portuguese version.

- *M* SV sodium thiosulfate is equivalent to 0,004904 g of $K_2Cr_2O_7$.

PACKAGING AND STORAGE
- In a hermetically closed container.

DERIVATIVE FORM
- **Starting point.** Potassium Bichromate ($K_2Cr_2O_7$).
- **Inert input.** Lactose in the 3 first centesimals and 6 first decimals, ethanol in several concentrations for the following.
- **Method.** *Hahnemannian Method (11.1), Korsakovian Method (11.2), Continuous Flow Method (11.3).*
- **Disposal.** From 1 DH trit. to 1 CH trit.
- **Packaging and storage.** In an amber, neutral container, tightly closed.

This translation does not replace the portuguese version.

KALI BROMATUM

- KBr; 119,02 [*7758-02-3*]
- Contains a minimal of 98,5% of KBr, in relation to the dry substance in a greenhouse at 105ºC, until constant weight.

HOMEOPATHIC SYNONYMY
- Kalium bromatum, Kalii bromidum, Potassii bromidum.

CHEMICAL NAME
- Potassium Bromide.

DESCRIPTION
- **Physical aspects.** Colorless, transparent or opaque, odorless, unalterable to air crystals, or white, grainy powder. Saline and spicy flavor.
- **Solubility.** Very soluble in water, slightly soluble in ethanol.
- **Incompatibilities.** Oxidant substances, mercury and silver salts and a few alkaloids salts.
- **Physical-chemical Constants.**
- *Fusion point* **(5.2.2) FB5**: 730 °C.

IDENTIFICATION

A. Small amount of the sample, dampened with hydrochloric acid, in platinum loop, taken to the non enlightening zone of the Bunsen Burner's flame, gives a violet color to it.

B. The sample's aqueous solution is neutral or slightly alkaline to the paper that indicates litmus.

C. Add 5 drops of sodium cobalt nitrite aqueous solution at 1% (p/v) to 2 mL of the sample's aqueous solution at 10% (p/v). A formation of yellow precipitate is observed.

D. Add 5 drops of silver nitrate aqueous solution at 1% (p/v) to 5 mL of the sample's aqueous solution at 10% (p/v). A formation of pale yellow, cheesy precipitate, slightly soluble in ammonium hydroxide aqueous solution at 10% (v/v).

E. Add 5 drops of lead acetate aqueous solution at 1% (p/v) to 5 mL of the sample's aqueous solution. A formation of crystal white precipitate, slightly soluble in cold water, but soluble in hot water, is observed.

PURITY TESTS
- **Barium and ammonium bromide.** Add 5 drops of sulfuric acid aqueous solution at 10% (v/v) to 1 mL of the sample's aqueous solution at 10% (p/v). Precipitation or even turbidity should not be observed.
- **Alkaline carbonates.** Grind a few milligrams of potassium bromide. Observe the grinded's reaction in relation to the paper indicator of red litmus, previously dampened with purified water. It should not become blue.
- **Iron.** Add enough amount of hydrochloric acid at 10% (v/v) to 2 mL of the sample's aqueous solution at 5% (p/v), to acidulate it. Add 5 drops of ferric chloride aqueous solution at 1% (p/v). It should not become blue.
- **Iodides.** Add 5 drops of ferric chloride aqueous solution at 1% (p/v) and a few drops of starch solution at 1% (p/v) to 2 mL of the sample's aqueous solution at 5% (p/v). The color violet-blue should not appear.

This translation does not replace the portuguese version.

- **Heavy metals.** Add 5 drops of sodium sulfide aqueous solution at 5% (p/v) to 2 mL of the sample's aqueous solution at 5% (p/v). Precipitation or turbidity is not observed.
- **Sodium.** Small amount of the substance, dampened with hydrochloric acid, in platinum loop, taken to the non enlightening zone of the Bunsen Burner's flame, should not become yellow.
- **Sulfates.** Add 5 drops of barium chloride aqueous solution at 1% (p/v) to 2 mL of the sample's aqueous solution at 5% (p/v). Precipitation or turbidity should not be observed.

DOSAGE

- Use one of the following methods:

A. Weigh 0.4 g of potassium bromide, previously desiccated in a greenhouse at 105ºC for 2 hours. Dissolve it in 40 mL of purified water, add 2 mL of 2 *M* nitric acid and 50 mL of 0.1 *M* SV silver nitrate aqueous solution. Titrate the excess of silver nitrate with 0.1 *M* SV potassium thiocyanate, using SR ferric ammonium sulfate as indicator. Each mL of silver nitrate is equivalent to 0.0119 g of KBr.

B. Weigh 0.3 g of potassium bromide, previously desiccated in a greenhouse at 105ºC for 2 hours. Dissolve it in 40 mL of purified water. Titrate with 0.1 *M* SV silver nitrate, using SR potassium chromate as indicator. Each mL of silver nitrate solution is equivalent to 0.011901g of KBr.

PACKAGING AND STORAGE

- In a neutral glass container, hermetically closed, away from humidity.

DERIVATIVE FORM

- **Starting point**. Potassium bromide (KBr).
- **Inert input.** In the first 3 centesimal and first 6 decimal streamlines, use the same alcohol level as mother tincture.
- **Method.** *Hahnemannian Method* **(11.1)**, *Korsakovian Method* ***(11.2),*** *Continuous Flow Method* ***(11.3).***
- **Disposal.** From 1 DH and 1 CH.
- **Packaging and storage.** In an amber, neutral container, tightly closed.

This translation does not replace the portuguese version.

KALI IODATUM

- KI; 166,00 [*7681-11-0*]
- Contains a minimal of 99.0% and maximum 100.5% of KI, in relation to the desiccated substance.

HOMEOPATHIC SYNONYMY
- Kalium iodatum, Kalii iodidum.

CHEMICAL NAME
- Potassium Iodide.

DESCRIPTION
- **Physical aspects.** White powder or colorless crystals.
- **Solubility.** Very soluble in water, easily soluble in glycerol and soluble in ethanol.

Physical-chemical Constants.
- *Fusion point* **(5.2.2) FB5**: 639 °C.

IDENTIFICATION
A. The sample's solution at 10% (p/v) in water free from carbon dioxide responds to the iodide ion's reactions **(5.3.1.1) FB 5**.
B. The sample's solution at 10% (p/v) in water free from carbon dioxide responds to the potassium ion's reactions **(5.3.1.1) FB 5**.

DOSAGE
- Weigh exactly about 1.5 g of the sample, dissolve it in water and complete the volume to 100 mL using the same solvent. Add 40 mL of concentrated hydrochloric acid to 20 mL of this solution and titrate it with 0.05 *M* SV potassium iodide until the color changes from brown to yellow. Add 5 mL of chloroform. Continue the titration, shaking vigorously, until the chloroformic layer discolorates. Each mL of 0.05 *M* SV potassium iodide is equivalent to 16.600 mg of KI.

PACKAGING AND STORAGE
- In a neutral glass container, with abraded lid, away from sunlight and heat.

FORMA DERIVADA
- **Starting point.** Potassium iodide (KI).
- **Inert input.** Hydroalcoholic solution in different grades, starting with 30% (v/v).
- **Method**. *Hahnemannian Method* **(11.1)**, *Korsakovian Method* **(11.2)**, *Continuous Flow Method* **(11.3)**.
- **Disposal.** From 1 CH and1 DH.
- **Packaging and storage.** In an amber, neutral container, tightly closed.

This translation does not replace the portuguese version.

KALI MURIATICUM

- KCl; 74,55 [*7447-40-7*]
- Contains a minimal of 99% of KC1 in relation to the substance preciously dry in a greenhouse at 105 °C, until constant weight.

HOMEOPATHIC SYNONYMY
- Kalium muriaticum, Kalii chloridum, Kalium chloratum.

CHEMICAL NAME
- Potassium chloride.

DESCRIPTION
- **Physical aspects.** Cubic, **e**longate prismatic crystals, colorless or even white powder. Odorless, of saline flavor and slightly bitter. It's aqueous solution is neutral to the indicative litmus. Stable to air.
- **Solubility.** Soluble in water, very soluble in hot water, soluble in ethanol at 90% (v/v). Insoluble in anhydrous ethanol.
- **Incompatibilities.** Silver, lead, mercury salts.

IDENTIFICATION
A. Small amount of the substance, dampened with hydrochloric acid, in platinum loop, taken to the non enlightening zone of the Bunsen Burner's flame, gives it a violet color.
B. Add 5 drops of sodium cobalt nitrite aqueous solution at 1% (p/v) to 2 mL of the sample's aqueous solution at 10% (p/v). A formation of yellow precipitate is observed.
C. Add 5 drops of silver nitrate aqueous solution at 1% (p/v) to 2 mL of the sample's aqueous solution at 10% (p/v). A formation of white precipitate, soluble in excess of ammonium hydroxide, is observed.
D. Then, add enough amount of nitric acid solution at 10% (v/v). Another precipitation of silver chloride is observed. Add 5 drops of potassium iodide aqueous solution at 1% (p/v). A formation of yellow precipitate is observed.

PURITY TESTS
- **Barium.** Add 5 drops of sulfuric acid aqueous solution at 10% (v/v) to 2 mL of the sample's aqueous solution at 10% (p/v). There should be no precipitation or even turbidity.
- **Bromides.** Separate the aqueous phase from the *Iodides test*. Add to it drops of sulfochromic mixture at 10% (p/v) in sulfuric acid at 25% (v/v). Add 2 mL of carbon tetrachloride. Shake vigorously. The phase formed by the carbon tetrachloride should not become yellow.
- **Calcium.** Add 5 drops of ammonium hydroxide and 5 drops of ammonium oxalate aqueous solution at 1% (p/v) to 2 mL of the sample's aqueous solution at 10% (p/v). There should not be any precipitation or turbidity.
- **Alkali Carbonates.** Grind a few milligrams of potassium chloride. Observe the grinded's reaction in relation to the red litmus indicator paper, previously dampened with purified water. It should not become blue.
- **Iron.** Add enough amount of hydrochloric acid at 10% (v/v) to 2 mL of the sample's aqueous solution at 5% (p/v), to acidulate it. Add 5 drops of ferric chloride aqueous solution at 1% (p/v). It does not become blue.

This translation does not replace the portuguese version.

- **Iodides.** Dissolve 1 g of potassium chloride in purified water. Add 2 mL of hydrochloric acid solution at 25% (v/v) and 5 drops of ferric chloride aqueous solution at 1% (p/v). After 5 minutes, add 2 mL of carbon tetrachloride. Shake vigorously. The carbon tetrachloride phase should not become violet.
- **Heavy metals.** Add 5 drops of sodium sulfide solution at 5% (p/v) to 2 mL of the sample's aqueous solution at 5% (p/v). No precipitation or turbidity should be observed.
- **Sodium.** Small amount dampened with hydrochloric acid, in platinum loop, taken to the non enlightening zone of the Bunsen Burner's flame, should not give it a yellow color.
- **Sulfates.** Add 5 drops of barium chloride aqueous solution at 1% (p/v) to 2 mL of the sample's aqueous solution at 5% (p/v). There should not be any precipitation or turbidity.

DOSAGE

- Weigh 0.25 g of the sample, dissolve it in 50 mL of purified water and titrate it with 0.1 *M* SV silver nitrate, using SR potassium chromate as indicator. Each mL of 0.1 *M* SV silver nitrate is equivalent to 0.007455 g of KCl.

PACKAGING AND STORAGE

- In amber, neutral glass container, hermetically closed.

DERIVATIVE FORM

- **Starting point.** Potassium chloride (KC1).
- **Inert input.** Hydroalcoholic solution in different grades.
- **Method.** *Hahnemannian Method* **(11.1)**, *Korsakovian Method* **(11.2)**, *Continuous Flow Method* **(11.3)**.
- **Disposal.** From 1 DH and 1 CH. The 1 DH and 1 CH should be prepared in purified water (extemporaneous preparation) and the 3 DH and 2 CH, in ethanol at 30%.
- **Packaging and storage.** In amber, neutral glass container, hermetically closed.

This translation does not replace the portuguese version.

KALI PHOSPHORICUM

- KH_2PO_4; 136,1 [*7778-77-0*]
- It contains a minimal of 99.0% and a maximum of 100.5% of KH_2PO_4.

HOMEOPATHIC SYNONYMY
- Kalium phosphoricum, Phosphas potassicus.

CHEMICAL NAME
- Potassium dihydrogen phosphate, biacid potassium phosphate, monobasic potassium phosphate.

DESCRIPTION
- **Physical aspects.** Colorless crystals or white powder, odorless.
- **Solubility.** Soluble in water and practically insoluble in ethanol.
- **Incompatibilities.** Alkaloids, it's salts and derivatives; silver, magnesium, barium and iron salts (III).
- **Physical-chemical Constants.**
- *Relative density* **(5.2.5) FB 5**: 2,34 g/mL to 20 °C.
- *Fusion point* **(5.2.2) FB 5**: 253 °C, with decomposition.

IDENTIFICATION
A. The sample's solution responds to the potassium ion **(5.3.1.1) FB 5**.
B. The sample's solution responds to the phosphate ion **(5.3.1.1) FB 5**.

PURITY TESTS
- **Solution aspects.** Dilute 5 mL of the *Solution (1),* described below, in 5 mL of purified water. The solution is clear **(5.2.25) FB 5** and colorless **(5.2.12) FB 5**.
  - *Solution (1)*: dissolve 20 g of the sample in purified water and complete the volume to 100 mL using the same solvent.
- **pH.** Dilute 1 mL of the *Solution (1)*, described on *Solution aspect, into 10 mL, using purified water.* This solution presents pH between 4.3 and 4.5.
- **Chlorides.** Transfer 1 mL of 0.01 *M* SV hydrochloric acid to a Nessler tube. Add 1 mL of nitric acid at 12.6% (p/v) and 1 mL of 0.1 *M* silver nitrate solution. Complete the volume to 50 mL. Transfer 48 mL of the *Solution*
- *(1)*, described in the *Solution Aspect*, to another Nessler tube. Add 1 mL of nitric acid at 12.6% (p/v) and 1 mL of 0.01 *M* silver nitrate solution and complete the volume to 50 mL. Leave both tubes quiescent and away from light for 5 minutes. The turbidity in the tube with the sample should not be superior to the one in the tube that contains the 0.01 *M* SV hydrochloric acid. A maximum of 0.012% (120 ppm).
- **Iron (5.3.2.4) FB 5.** Dilute 1 mL of the *Solution (1)*, described on *Solution aspect, into 10 mL, using purified water.* Proceed as described in the *Iron Limit Test*. A maximum of 0.005% (50 ppm).
- **Heavy metals (5.3.2.3) FB 5**. Use *Method I*. Proceed as described in *Heavy Metals Limit Test*. A maximum of 0.001% (10 ppm).
- **Sulfates (5.3.2.2) FB 5.** With 15 mL of the *Solution (1)*, described in *Solution Aspect*, proceed as described in *Sulfates Limit Test*. A maximum of 0.005% (50 ppm).

This translation does not replace the portuguese version.

DOSAGE

- Dissolve about 0.2 of the sample, weighed with 1 mg precision, in 100 mL of purified water. Add 0.2 mL of SI thymol blue and titrate with 0.1 *M* SV sodium hydroxide until the color is the same as a standard solution with pH 9.2, prepared with 97 mL of 0.05 *M* sodium tetraborate solution, 3 mL of 0.1 *M* hydrochloric acid solution and 0.2 mL of SI thymol blue. Each mL of 0.1 *M* SV sodium hydroxide is equivalent to 0.014 g
- of KH_2PO_4.

PACKAGING AND STORAGE

- In amber, neutral glass container, hermetically closed.

DERIVATIVE FORM

- **Starting point.** Monobasic Potassium Phosphate **(KH_2PO_4).**
- **Inert input.** Use lactose up to 3 CH or 6 DH and, for other ones, follow the general rule of preparation of derivative pharmaceutical forms.
- **Method.** *Hahnemannian Method* **(11.1)**, *Korsakovian Method* **(11.2)**, *Continuous Flow Method* **(11.3)**.
- **Disposal.** From 1 CH or 1 DH, following the general rule of disposal.
- **Packaging and storage.** In amber, neutral glass container, hermetically closed.

This translation does not replace the portuguese version.

LACTOSE

- $C_{12}H_{22}O_{11}$; 342,30 [*63-42-3*]

CHEMICAL NAME
- 4-O-β-D-galactopiranosil-D-glicose.

DESCRIPTION
- **Physical aspects.** White crystals, crystalline masses or white, odorless, slightly sweet, stable to air powder; rapidly absorbs odors from it's surroundings.
- **Solubility.** Soluble in cold water, very soluble in boiling water, practically insoluble in ethanol, insoluble in ethyl ether and chloroform.
- **Physical-chemical Constants.**
- *Relative density* **(5.2.5) FB 5**: 1,53.
- *Specific rotational power* **(5.2.8) FB 5**: +54,8° to +55,9°, calculated in relation to the dry substance, determined in 10 g lactose solution with 0.2 mL of ammonium hydroxide for each milliliter of the solution.
- *Fusion temperature* **(5.2.2) FB 5**: 201 °C to 202 °C, with decomposition.

IDENTIFICATION

A. Add 5 mL of 0.1 M sodium hydroxide to 5 mL of a heated lactose saturated solution. Slightly heat it. A yellow color is develop, which turns into reddish-brown.

B. Add 2 mL of SR sodium hydroxide and 3 drops of SR cupric sulfate to 5 mL of the lactose solution at 1% (p/v). The solution becomes blue and clear. Heat it until it boils. A red precipitate is formed.

C. Heat 5 mL of lactose aqueous solution at 5% (p/v) with 5 mL of ammonium hydroxide concentrated and saturated with ammonium chloride. Heat it in water bath at 80ºC for 10 minutes. A red color appears.

D. Add 0.4 g of phenylhydrazine hydrochloride, 0.6 g of crystallized sodium acetate and 4 mL of purified water to 0.2 g of lactose. In a tube with a lid, heat it in boiling water bath. Occasionally shake the tube without removing it from the bath. The formation of a yellow crystalline precipitate that decomposes at 200ºC is observed.

PURITY TESTS
- **Solution aspects.** Dissolve 1 g of lactose in 10 mL of boiling purified water. The solution is clear **(5.2.25) FB 5** practically colorless **(5.2.12) FB 5** and odorless.
- **pH (5.2.19) FB 5.** 4,0 to 6,5. Determine in the sample's solution at 10% (p/v).
- **Starch or dextrin.** Dissolve 1 g of lactose in 10 mL of purified water. Let it boil for 1 minute and then cool at ambient temperature. Add 1 drop of SR iodide. It should not become red, blue or violet.
- **Sucrose and glucose.** Add 5 g of finely divided lactose to 20 mL of ethanol at 25% (v/v). Shake vigorously for 5 minutes. Filter. Evaporate 10 mL of the filtered substance until its dry. Dry the residue in a greenhouse at 100ºC for 10 minutes. The residue should not be greater than 20 mg.
- **Arsenic (5.3.2.5) FB 5.** A maximum of 0.0001% (1 ppm).
- **Heavy metals (5.3.2.3) FB 5.** Use *Method I*. Dissolve 4 g of lactose, at high temperature, in 20 mL of purified water. Add 1 mL of 0.1 *M* hydrochloric acid. Dilute it with purified water

This translation does not replace the portuguese version.

until it reaches 25 mL of volume. Compare with standard as described in *Heavy Metals Limit Test*. A maximum of 0.0005% (5 ppm).

- **Sulphated ash (5.2.10) FB 5.** A maximum of 0.1%.
- **Packaging and storage.** In a container hermetically closed, away from humidity, gases and odoriferous fumes.

This translation does not replace the portuguese version.

LOBELIA INFLATA

- *Lobelia inflata* (L.) – CAMPANULACEAE

HOMEOPATHIC SYNONYMY
- Lobelia, Rapuntium inflatum, Rapuntium inflatus.

PART EMPLOYED
- Entire dry plant.

PLANT DESCRIPTION
- *Lobelia inflata* L. is an annual or biannual herbaceous plant, with a yellowish white, slender, fibrous root. Stem 20 cm to 60 cm high, round, erect, striated, filled with leaves, paniculately branched on the top and hirsute on the bottom, relatively angular. Alternate leaves, irregularly arranged, with petiolate lower ones, and the rest, sessile, venous, oval or oblong with foliated bracts or subulate on the top, sharp and irregularly toothed, slender, pubescent and of light green color. The flowers have a light blue tone, are small, irregular in leafy terminal racemes similar to an ear of corn, each one untied in the axil of a small leaf. The plant secrets milky, acre and toxic latex. It's fruits have a length of 5 mm to 8 mm, are striated, of a light brown, bilocular with numerous reticulated, oval, oblong and brown seeds, with a length of 5 mm to 7 mm, faint odor and accentuated acre flavor, resembling tobacco.

DRUG DESCRIPTION
- The drug presents the characters in the plant description.

PREPARATION OF MOTHER TINCTURE
- Proceed as described in *Preparation of mother tincture of vegetable origin* **(10.1).** The *Lobelia inflata* mother tincture is prepared by maceration or percolation, so the alcohol level during and at the end of the extraction is of 65% (v/v), according to the preparation of mother tincture's general technique.

MOTHER TINCTURE FEATURES
- Yellowish or dark green liquid, with no particular odor.

IDENTIFICATION

A. Add 0.2 mL of potassium hydroxide ethanolic solution at 10% (p/v) to 5 mL of mother tincture and distill to attain 2 mL of distillate. Add 0.1 g of 1.3- dinitrobenzene and 0.2 mL of potassium hydroxide solution at 10% (p/v) to the product, boil it for 1 minute. A red color appears.

B. To 1 mL of mother tincture add 1 mL of sodium hydroxide solution at 10% (p/v) and 0.5 mL of a mixture of 0.1 g of sulfanilic acid, 0.1 g of sodium nitrite, 1 mL of purified water and 1 mL of hydrochloric acid at 10% (v/v). A red color appears.

C. Proceed as described in Chromatography in slender layer **(5.2.17.1) FB 5**, using G silica-gel as support and toluene, ethyl acetate and diethylamine mixture (7:2:1) as mobile phase. Apply to the plate 20 mL of the *Sample Solution* recently prepared, described below.
  – *Sample Solution:* evaporate 5 mL of mother tincture in water bath until the ethanol odor disappears, add 1 mL of ammonium hydroxide and extract twice, each time with 10 mL

This translation does not replace the portuguese version.

of ethyl ether. Evaporate and unite the ethereal phases in water bath. Dissolve the residue in 0.5 mL of methanol.

- Develop the chromatogram through 10 cm. Remove the plate, leave it to dry. Nebulize the plate with iodoplatinate reagent. Immediately examine under natural light. The chromatogram obtained with the *Sample Solutio*n presents a light brown stain with Rf close to 0.65 (lobeline).

PURITY TESTS

- **Title in ethanol.** Must be between 60% and 70% (v/v).
- **Dry residue.** Must be greater or equal to 1.3% (p/v).

PACKAGING AND STORAGE

- In an amber, neutral glass container, tightly closed, away from light and heat.

DERIVATIVE FORM

- **Starting point.** Mother tincture.
- **Inert input.** From 1 CH to 3 CH or 1 DH to 6 DH use the mother tincture same alcohol level.
- For others dilutions, follow the general rule of derivative pharmaceutical forms preparation.
- **Method.** *Hahnemannian Method* **(11.1)**, *Korsakovian Method* **(11.2)**, *Continuous Flow Method* **(11.3)**.
- **Disposal.** From 1 CH or 2 DH, following the general rule of disposal.
- **Packaging and storage.** In an amber, neutral glass container, tightly closed, away from light and heat.

This translation does not replace the portuguese version.

LYCOPODIUM CLAVATUM

- *Lycopodium clavatum* (L.) – LYCOPODIACEAE

HOMEOPATHIC SYNONYMY
- Lycopodium piliferum, Muscus squamosus, Muscus clavatus, Muscus ursinus, Pes leoninus, Pes ursinus.

PART EMPLOYED
- Dry spores.

PLANT DESCRIPTION
- *Lycopodium clavatum* L. is a perennial creeping plant, with roots of several strong and spread fibers, that resembles a wolf's paw. The stem crawls extensively and sparsely issues single, direct, simple and smooth buds, with very leafy ascending branches, a fertile tip in a slender peduncle, bearing 2 or 3 linear and cylindrical stalks. On the scales axis are very small spores, more or less flat, reniform, coriaceous, unicellular, forming a pale-yellow powder, which is odorless, tasteless, floats over water and not capable of wetting, presenting under microscope reticulated grains with 4 sides, with short juts on the edges. When ground, the spores capsules are torn, transforming it in an unctuous mass of a bright yellow color.

DRUG DESCRIPTION
- It is comprised of a fine, pale yellow, odorless and tasteless powder, which is very movable and floats on water, and sputters when exposed to fire. Under microscope is observed a tetrahedral reticulate grain with small juts on it's angle.

PREPARATION OF MOTHER TINCTURE
- Proceed as described in *Preparation of mother tincture of vegetable origin* **(10.1).** The *Lycopodium clavatum* L mother tincture is prepared by maceration or percolation, so the alcohol level during and at the end of the extraction is of 90% (v/v), according to the preparation of mother tincture's general technique.

MOTHER TINCTURE FEATURES
- Pale-yellow liquid, with no typical odor and with a flavor that resembles an oily substance.

IDENTIFICATION
A. Add 1 mL of purified water to 1 mL of mother tincture. A milky turbidity is observed.
B. Add 0.3 mL of SR phloroglucin and 1 mL of hydrochloric acid at 25% (p/v) to 1 mL of mother tincture. If the solution is heated, a change in color is observed, from pink to orange yellow.
C. Add 1 mL of concentrated sulfuric acid in a test-tube, then slowly add 1 mL of mother tincture through it's walls. The formation of 2 phases is observed, with a red color between them.
D. Add 0.2 mL of sodium hydroxide solution at 1% (p/v) to 1 mL of mother tincture. An intense blue fluorescence is observed under ultraviolet light (365 nm), which disappears with the addition of drops of hydrochloric acid at 10% (p/v).
E. Proceed as described in *Chromatography in slender layer* **(5.2.17.1) FB 5**, using G silica-gel as support and a mixture of acetic acid anhydride, ethyl ether and petroleum ether (5:35:60)

This translation does not replace the portuguese version.

as mobile phase. Apply to the plate 10 mL of the *Standard Solution* recently prepared, described below.

– Standard Solution: dissolve 30 mg of vanillin, 30 mg of carvone and 10 mg of scopoletin in 10 mL of methanol.

- Develop the chromatogram through 10 cm. Remove the plate, leave it to dry. In a lab, put the plate in a vat containing iodide crystals saturating with it's fumes, until the brown stain is visible. Remove the excess iodide in a cold air draft. Nebulize with a starch solution at 1% (p/v). Examine under day light. The brown stain changes to blue.

PURITY TESTS

- **Title in ethanol.** Must be between 85% and 95% (v/v).
- **Dry residue.** Must be greater or equal to 1.2% (p/v).

PACKAGING AND STORAGE

- In an amber, neutral glass container, tightly closed, away from light and heat.

DERIVATIVE FORM

- **Starting point.** Mother tincture.
- **Inert input.** From 1 CH to 3 CH or 1 DH to 6 DH use the mother tincture same alcohol level. For others dilutions, follow the general rule of derivative pharmaceutical forms preparation.
- **Method.** *Hahnemannian Method* **(11.1)**, *Korsakovian Method* **(11.2)**, *Continuous Flow Method* **(11.3)**.
- **Disposal.** From mother tincture, following the general rule of disposal.
- **Packaging and storage.** In an amber, neutral glass container, tightly closed, away from light and heat.

This translation does not replace the portuguese version.

MAGNESIA CARBONICA

- $(MgCO_3)_4Mg(OH)_2.5H_2O$; 544,04 [*39409-82-0*]
- The magnesium carbonate is the basic carbonate of hydrous magnesium. It contains the equivalent of a minimal of 40% and a maximum of 43% of magnesium oxide (MgO). Minimal of 24% of magnesium.

HOMEOPATHIC SYNONYMY
- Magnesii subcarbonas, Magnesium carbonicum, Magnesium carbonate, Carbonas magnesicus.

CHEMICAL NAME
- Basic pentahydrate magnesium carbonate

DESCRIPTION
- **Physical aspects.** Solid odorless white.
- **Solubility.** Insoluble in water and ethanol. Soluble in acids diluted with effervescence.
- **Incompatibilities.** Diluted acids, hydroxides, soluble alkaline phosphates, alkali carbonates and bicarbonates.
- **Physical-chemical Constants.**
- *Relative density* **(5.2.5) FB 5**: 2,16g/mL.
- *Temperature of decomposition*: are decomposed in MgO at 700ºC.

IDENTIFICATION
A. When treated with 3 *M* hydrochloric acid is dissolved with strong effervescence, resulting a solution that responds to the reactions of magnesium identification **(5.3.1.1) FB 5**.
B. The hydrous magnesium carbonate responds to the reactions of carbonate identification **(5.3.1.1) FB 5**.

PURITY TESTS
- **Arsenic (5.3.2.5) FB 5.** Dissolve 5 g of the sample in 100 mL of 2 *M* acetic acid solution. When the effervescence is finished, boil for 2 minutes, cool it and take the volume up to 100 mL with the same acid. Filter, if necessary, through a sintered glass filter. With 10 mL of the solution, proceed as described in *Arsenic Limit Test*. A maximum of 0.0002% (2 ppm).
- **Calcium.** Transfer 0.3 g of the sample, weighed with 1 mg precision, dampen with purified water, dissolve with *M* hydrochloric acid until no more gas is produced. Add 5 mL of 5 M sodium hydroxide solution and 5 mL of SI chalcone. Titrate with 0.05 *M* SV edetate disodium until the color changes from purple-red to blue. Each mL of 0.05 *M* SV edetate disodium is equivalent to 0.002 g of Ca2+. A maximum of 0.1% (1000 ppm).
- **Chlorides (5.3.2.1) FB 5.** Dilute 3.3 mL of the solution prepared on the *Arsenic* test in *Purity Tests*, with purified water until the volume reaches 15 mL. A maximum of 0.03% (300 ppm).
- **Iron (5.3.2.4) FB 5.** Dissolve 0.1 g of the sample in 3 mL of 2 *M* hydrochloric acid solution and add purified water until the volume reaches 10 mL. Transfer 2.5 mL of this solution to another flask and add purified water until the volume reaches 10 mL. A maximum of 0.04% (400 ppm).
- **Sulfates (5.3.2.2) FB 5.** Dilute 1 mL of the solution prepared on the *Arsenic* test in *Purity Tests*, with purified water until the volume reaches 15 mL. A maximum of 0.3% (3000 ppm).

This translation does not replace the portuguese version.

- **Soluble substances.** Mix 2 g of the substance with 10 mL of purified water, boil for 5 minutes, filter while hot, let it cool and add purified water until the volume reaches 100 mL. Evaporate 50 mL of the filtered substance until it dries, at a temperature between 100ºC and 105ºC, until constant weight. The residue should not be greater than 0.01 g.
- **Substances insoluble in acids.** Mix 10 g of the sample with 75 mL of purified water, add 2 *M* hydrochloric acid in small amounts, with constant agitation until total dissolution of the magnesium carbonate (effervescence not occurring). Boil for 5 minutes. If there is any insoluble residue, filter and wash it with purified water until every liquid is free from chloride (test with AgNO3). The weight of the residue, in case it exists, after burn, must not exceed 0.005 g, i.e., 0.05% (p/p).

DOSAGE

- Dampen approximately 0.5 g of the sample (weighed with 1 mg precision) with 20 mL of purified water, add 50 mL of *M* SV hydrochloric acid. Titrate the excess acid with *M* sodium hydroxide standardized solution until it becomes pink, using SI phenolphthalein as indicator. Each mL of *M* SV hydrochloric acid that reacted with the sample is equivalent to 0.020 g of MgO.

PACKAGING AND STORAGE

- In an amber and neutral container, tightly closed.

DERIVATIVE FORM

- **Starting point.** Magnesium carbonate $(MgCO_3)_4Mg(OH)_2.5H_2O$.
- **Inert input.** Use lactose up to 3 CH or 6 DH and, for other ones, follow the general rule of preparation of derivative pharmaceutical forms.
- **Method.** *Hahnemannian Method* **(11.1)**, *Korsakovian Method* **(11.2)**, *Continuous Flow Method* **(11.3)**.
- **Disposal.** From 1 CH or 1 DH, following the general rule of disposal.
- **Packaging and storage.** In amber, neutral glass container, hermetically closed.

This translation does not replace the portuguese version.

MAGNESIA MURIATICA

- $MgCl_2.6H_2O$; 203,33 [*7791-18-6*]
- It contains a minimal of 98.0% and a maximum of 101.0% of $MgCl_2.6H_2O$.

HOMEOPATHIC SYNONYMY
- Magnesia hydrochlorica, Magnesii chloridum. Magnesium chloratum.

CHEMICAL NAME
- Magnesium chloride hexahydrate.

DESCRIPTION
- **Physical aspects.** Colorless, odorless and hygroscopic crystals.
- **Solubility.** Soluble in water (1,67:1) and in ethanol.
- **Incompatibilities.** Alkalies in general, alkali carbonates and bicarbonates, soluble alkaline phosphates.
- **Physical-chemical Constants.**
- *Relative density* **(5.2.5) FB 5**: 1,57 g/mL to 20 °C.

IDENTIFICATION

A. For chloride identification, treat solution of the sample acidified with nitric acid, with SR silver nitrate. A white precipitate, insoluble in nitric acid, but soluble in 6 *M* ammonium hydroxide, is formed.

B. For magnesium identification, treat solution of the sample with sodium hydroxide solution at 8% (p/v). A white precipitate that dissolves with addition of 2 *M* ammonium chloride is formed.

PURITY TESTS
- **Solution aspects.** The *Solution (1)* described below is clear **(5.2.25) FB 5** and colorless **(5.2.12) FB 5**.
  – *Solution (1)*: dissolve 10 g of the sample in enough amount for 100 mL of purified water.
- **pH.** Add 0.1 mL of SI phenol red to 5 mL of the Solution (1), described in *Solution Aspect* of *Purity Tests*. No more than 0.3 mL of 0.01 M sodium hydroxide solution or of hydrochloric acid should be enough to change the solution's color.
- **Arsenic (5.3.2.5) FB 5.** 5 mL of the Solution (1), described in *Solution Aspect* of *Purity Tests*, should satisfy the *Arsenic Limit Test*. A maximum of 0.0002% (2 ppm).
- **Barium.** Dissolve 1 g of the sample in 10 mL of purified water. Add 1 mL of M sulfuric acid solution. It should not produce any turbidity within 2 hours.
- **Calcium.** Transfer 0.3 g of the sample, weighed with 1 mg precision, dissolve in 50 mL of purified water, add 5 mL of 5 M sodium hydroxide solution and 5 mL of SI chalcone. Titrate with 0.05 *M* SV edetate disodium until the color changes from purple-red to blue. Each mL of 0.05 *M* SV edetate disodium is equivalent to 0.002 g of Ca2+. A maximum of 0.1%. (1000 ppm).

DOSAGE
- Transfer to an erlenmeyer approximately 0.3 g of the sample, weighed with 1 mg precision. Dissolve in 50 mL of purified water. Add 10 mL of ammonium chloride buffer pH 10.0 and

This translation does not replace the portuguese version.

about 10 mL of eriochrome black T SI. Titrate with 0.05 *M* SV edetate disodium until the color changes from violet to blue. Denominate the volume consumed in this titration as *V1*.

- Transfer 0.3 g of the sample, weighed with 1 mg precision, to another erlenmeyer, dissolve it in 50 mL of purified water. Add 5 mL of 5 M sodium hydroxide solution and 5 mL of SI chalcone. Titrate with 0.05 *M* SV edetate disodium until the color changes from purple-red to blue. Denominate the volume consumed in this titration as *V2*. This volume corresponds to the calcium level.
- The difference between V1 and V2 is the volume of the edetate disodium 0.05 *M* SV that made the sample complex and corresponds to the magnesium level of the sample. Each mL of 0.05 *M* SV edetate disodium is equivalent to 0.001 g of $MgCl_2.6H_2O$

PACKAGING AND STORAGE

- In an amber and neutral container, tightly closed.

DERIVATIVE FORM

- **Starting point.** Magnesium chloride hexahydrate ($MgCl_2.6H_2O$).
- **Inert input.** Use alcohol at 70% (v/v) up to 3 CH or 6 DH and, for other ones, follow the general rule of preparation of derivative pharmaceutical forms.
- **Method.** *Hahnemannian Method* **(11.1)**, *Korsakovian Method* **(11.2)**, *Continuous Flow Method* **(11.3)**.
- **Disposal.** From 1 CH or 1 DH, following the general rule of disposal.
- **Packaging and storage.** In an amber, neutral glass container, tightly closed, away from light and heat.

This translation does not replace the portuguese version.

MAGNESIA PHOSPHORICA

- $MgHPO_4.3H_2O$; 174,33 [*7757-86-0*]
- It contains a minimal of 98.0% and a maximum of 102.0 % of $MgHPO_4.3H_2O$.

HOMEOPATHIC SYNONYMY
- Magnessi phosphas, Magnesium phosphoricum.

CHEMICAL NAME
- Magnesium mono hydrogen phosphate trihydrate, magnesium mono acid phosphate trihydrate, magnesium phosphate dibasic trihydrate.

DESCRIPTION
- **Physical aspects.** White, odorless and tasteless powder.
- **Solubility.** Practically insoluble in water, insoluble in ethanol and soluble in diluted acids.
- **Incompatibilities.** Alkalies in general, alkali carbonates and bicarbonates, soluble alkaline phosphates.

Physical-chemical Constants.
- *Relative density* **(5.2.5) FB 5**: 2,130g/mL to 20 °C.
- *Temperature of Decomposition:* Are decomposed at 550ºC.

IDENTIFICATION

A. A. In a spot plate, add 0.2 mL of SI titan yellow and 0.2 mL of the *Solution (1)*, described below. Add, drop by drop, 2 *M* sodium hydroxide solution. A red color is developed.
  – *Solution (1)*: dissolve 1.5 g of the sample in diluted hydrochloric acid at 5% (v/v) to produce a volume of 30 mL.

B. Add 2 mL of SR molibdovanadio to 1 mL of the *Solution (1)*, described in test **A.** of *Identification*. A yellow color is produced, and if the mixture is heated a slow formation of yellow precipitate is observed.

PURITY TESTS
- **Dibasic potassium phosphate and magnesium phosphate.** Dissolve 2 g of the substance in 30 mL of *M* SV hydrochloric acid, add 20 mL of purified water and 0.05 mL of SI methyl orange. Titrate the excess hydrochloric acid with *M* SV sodium hydroxide. The volume of the sodium hydroxide used in the titration corresponds to the excess hydrochloric acid. The volume of the hydrochloric acid consumed in the titration should not be lower than 11 mL and greater than 12.5 mL.
- **Arsenic (5.3.2.5) FB 5.** Determine it in 1 g of the substance. Must comply with the *Arsenic Limit Test*. A maximum of 0.0005% (5 ppm).
- **Chloride (5.3.2.1) FB 5.** Dissolve 0.25 g of the substance in a mixture of 5 mL of nitric acid at 5% (v/v) and 10 mL of purified water. The resulting solution must comply with the *Chlorides Limit Test*. A maximum of 0.2% (2000 ppm).
- **Sulfates (5.3.1.1) FB 5.** Add 5 mL of purified water to 10 mL of the *Solution (1)*, described in test **A.** of *Identification*. The attained solution must comply with the *Sulfates Limit Test*. A maximum of 0.03% (300 ppm).

This translation does not replace the portuguese version.

DOSAGE

- Dissolve approximately 0.2 g of salt, weighed with 1 mg precision, in 20 mL of purified water and 2 mL of M hydrochloric acid and heat it mildly until total dissolution. Add 40 mL of 0.1 *M* SV edetate disodium and purified water until it reaches 100 mL of volume. Neutralize with *M* sodium hydroxide solution. Add 3 mL of ammonium chloride buffer with pH 10.0 and a few milligrams of eriochrome black T. Titrate the excess 0.1 *M* SV edetate disodium with 0.1 M SV zinc sulfate, until the color changes from green to red.
- The difference between the volume of the 0.1 *M* SV edetate disodium added and the zinc sulfate's volume corresponds to the 0.1 *M* SV edetate disodium's volume that reacted with the magnesium compound.
- Each mL of 0.1 *M* SV edetate disodium is equivalent to 0.002 g of $MgHPO_4.3H_2O$.

PACKAGING AND STORAGE

- In amber, neutral glass container, hermetically closed.

DERIVATIVE FORM

- **Starting point.** Dibasic Magnesium Chloride ($MgHPO_4.3H_2O$).
- **Inert input.** Use lactose up to 3 CH or 6 DH and, for other ones, follow the general rule of preparation of derivative pharmaceutical forms.
- **Method.** *Hahnemannian Method* **(11.1)**, *Korsakovian Method* **(11.2)**, *Continuous Flow Method* **(11.3)**.
- **Disposal.** From 1 CH or 1 DH, following the general rule of disposal.
- **Packaging and storage.** In amber, neutral glass container, hermetically closed.

This translation does not replace the portuguese version.

MERCURIUS SULPHURATUS RUBER

- HgS; 232,68 [*1344-48-5*]
- It contains a minimal of 99% of HgS in relation to the substance dried in greenhouse at 100ºC, until constant weight.

HOMEOPATHIC SYNONYMY
- Cinnabaris, Hydrargyrum sulphuratum rubrum, Sulphuretum hydrargyricum.

CHEMICAL NAME
- Mercury sulfide, red.

DESCRIPTION
- **Physical -chemical aspects.** Heavy, bright scarlet, odorless, tasteless, very soft powder. It darkens when exposed to light and in the presence of water or alkaline hydroxides. It becomes black and volatile when heated.
- **Solubility.** Insoluble in water and ethanol. It dissolves in *aqua regia*, but it is insoluble in hydrochloric and nitric acids.
- **Incompatibilities.** Aluminum, sulfuric acid, nitric acid and chromium oxide.

IDENTIFICATION
A. Add 5 drops of barium chloride aqueous solution at 1% (p/v) to 5 mL of the *Solution (1)*, described below. The formation of white precipitate is observed.
  – *Solution (1):* Dissolve 0.1 g of the sample in 100 mL of aqua regia, in heat; add 10 mL of purified water.

B. Add 5 drops of stannous chloride aqueous solution at 1% (p/v) to 5 mL of the *Solution (1)*. The formation of gray precipitate is observed.

PURITY TESTS
- **Heavy metals (5.3.2.3) FB 5.** Use *Method I*. Shake 5 g of the sample with 5 mL of nitric acid at 10% (p/v) and heat it for 1 to 2 minutes. The liquid's color should remain unaltered. After cooling, filter, neutralize the filtered substance with ammonium hydroxide solution at 10% (p/v). Add 2 mL of diluted acetic acid and complete the volume of 50 mL with water. Proceed as described in the *Heavy Metals Limit Test*.
- **Sulfur, arsenic and antimony.** Heat 0.5 g of the sample with 20 mL of sodium hydroxide solution at 4% (p/v) at a temperature of 60ºC to 70ºC, for 5 minutes, shake and filter. Add 1 drop of lead acetate solution at 10% (p/v) to 5 mL of the filtered substance, and to the other 5 mL add hydrochloric acid to acidify it. No change should occur.
- **Loss by desiccation (5.2.9) FB 5.** When heated at 110ºC for 4 hours, a loss of weight greater than 0.2% should not occur.
- **Sulphated ash (5.2.10) FB 5.** Determine in 1 g. Should not present residue grater than 0.2%.

DOSAGE
- Carefully weigh 0.4 g of the sample previously dry at 110ºC for 4 hours. Transfer to a 300 mL Kjeldahl balloon, add 10 mL of sulfuric acid and 10 mL of nitric acid. Mildly heat the mixture until the brown fume is completely released. Cool it and carefully add 50 mL of water and drip SR potassium permanganate until a persistent red color appears. Add SR oxalic acid, drop by drop, and heat until discoloration. Cool it, add 3 mL of nitric acid

This translation does not replace the portuguese version.

and titrate it with 0.1 *M* SV ammonium thiocyanate, using SR ferric ammonium sulfate as indicator. Each mL of 0.1 *M* SV ammonium thiocyanate is equivalent to 11.63 mg of HgS.

PACKAGING AND STORAGE

- In an amber, neutral container, hermetically closed and away from light.

DERIVATIVE FORM

- **Starting point.** Mercury sulfide (HgS).
- **Inert input.** Lactose
- **Method.** *Hahnemannian Method* **(11.1)**, *Korsakovian Method* **(11.2)**, *Continuous Flow Method* (**11.3**).
- **Disposal.** From 4 DG trit. or 2 CH trit.
- **Packaging and storage.** In an amber and neutral container, tightly closed.

This translation does not replace the portuguese version.

NATRUM CARBONICUM

- $Na_2CO_3.H_2O$; 124,01 [*5968-11-6*]
- It contains a minimal of 83% and a maximum of 86% of Na_2CO_3.

HOMEOPATHIC SYNONYMY
- Katrina carbonas monohydricus, Carbonas natricus, Sodii carbonas, Natrium carbonicum.

CHEMICAL NAME
- Sodium carbonate monohydrate.

DESCRIPTION
- **Physical-chemical aspects.** Crystalline, colorless or white powder, odorless and of salty flavor. It's solution is alkaline. Stable to air in normal conditions and looses absorption water when exposed to dry air or above 50ºC and, when heated at 105ºC, looses it's crystallization water.
- **Solubility.** Soluble in water. Practically insoluble in ethanol.
- **Incompatibilities.** General acids, acid salts, alkaloids and it's salts and derivatives, general metallic salts, soluble calcium salts, barium, magnesium and strontium.
- **Physical-chemical Constants.**
- *Fusion point* **(5.2.2) FB 5**: 854 °C.
- *Relative density* **(5.2.5) FB 5**: 2,25 g/mL to 20 °C.

IDENTIFICATION
- A. Prepare the *Solution (1)*, described below. This solution is highly alkaline. The addition of 0.2 mL of SI phenolphthalein turns the solution red.
- *Solution (1)*: dissolve 1 g of the salt in purified water and dilute to 10 mL.
- Treat 1 g of the sample with 20 mL of *M* hydrochloric acid solution. A release of colorless gas is observed, which, when reacting with SR calcium hydroxide, immediately forms a white precipitate.
- Dampen the platinum loop with the *Solution (1)*, described in the *Identification* test **A.**, and place it in the reducing zone of the Bunsen burner. A non luminous flame of an intense yellow is observed, which is not seen when interposed by a cobalt blue glass blade.

PURITY TESTS
- **Alkali hydroxides and bicarbonates.** Dissolve 0.4 g of the sample in 20 mL of purified water, add 20 mL of barium chloride at 6% (p/v) and filter it. Add 0.1 mL of SI phenolphthalein to 10 mL of the filtered substance. The solution should not become red. Heat the rest of the filtered substance until ebullition for 2 minutes. The solution should remain clear.
- **Chlorides.** Prepare the solutions described below.
- *Sample Solution*: dissolve 0.4 g of the sample in purified water, add 4 mL of 2 *M* nitric acid and dilute to 15 mL with purified water. Pour this solution in a test-tube containing 1 mL of 0.1 *M* silver nitrate.
- *Standard Solution*: prepare another solution in the same way, using 10 mL of chloride standard solution (5 ppm Cl) in 5 mL of purified water.
- Leave the tubes protected from light and after 5 minutes examine them sideways against a dark background. The opalescence observed in the *Sample Solution* should not be more intense than the one in the *Standard Solution*.

This translation does not replace the portuguese version.

- **Loss by desiccation (5.2.9) FB 5.** Desiccate 1 g of the salt to a temperature between 100ºC and 105ºC for 2 hours. It should not loose less than 13.8% and more than 15.2% of it's mass.

DOSAGE
- Dissolve about 0.2 of salt, weighed with 1 mg precision, in 25 mL of purified water. Add 0.5 mL of SI bromocresol green and titrate, slowly and with constant agitation, with *M* SV hydrochloric acid until the solution changes to a green color. Heat the solution to ebullition for 2 minutes, cool it and continue the titration until a yellow color appears. Each mL of *M* SV hydrochloric acid corresponds to 0.053 g of Na_2CO_3.

PACKAGING AND STORAGE
- In an amber, neutral glass container, tightly closed, away from light and heat.

DERIVATIVE FORM
- **Starting point.** Sodium carbonate monohydrate ($Na_2CO_3.H_2O$).
- **Inert input.** Use lactose up to 3 CH or 6 DH and, for other ones, follow the general rule of preparation of derivative pharmaceutical forms.
- **Method.** *Hahnemannian Method* **(11.1)**, *Korsakovian Method* **(11.2)**, *Continuous Flow Method* **(11.3)**.
- **Disposal.** From 1 CH or 1 DH, following the general rule of disposal.
- **Packaging and storage.** In amber, neutral glass container, hermetically closed.

This translation does not replace the portuguese version.

NATRUM MURIATICUM

- NaCl; 58,44 [*7647-14-5*]
- Contains at least 99.4% of NaCl, calculated in relation to the desiccated substance for 1 hour at 250 - 300 °C.

HOMEOPATHIC SYNONYMS
- Natrum chloratum, Natrii chloridum, Natrii chloridum crudum, Natrium muriaticum crudum, Natrum muriaticum marinum, Natrium muriaticum, Natrii chloretum.

CHEMICAL NAME
- Sodium chloride.

DESCRIPTION
- **Physical characteristics.** The sea salt, gross non purified product, assumes the shape of slightly grayish crystals, odorless, salty flavored and hygroscopic. Whenever heated, it loses water and decrepitates. The sea salt commonly contains small quantities of potassium chloride and magnesium chloride, traces of calcium, aluminum and several other metals. The sodium chloride distinguishes itself from the sea salt as it assumes the shape of cubic colorless crystals or white crystalline powder, odorless, salty flavored and a little hygroscopic.
- **Solubility.** Easily soluble in water, soluble in glycerol, slightly soluble in ethanol.
- **Incompatibilities.** Sulphuric acid, silver soluble salts, mercurous salts and lead soluble salts.

Physicochemical constants.
- *Fusion point* **(5.2.2) FB 5**: 801 °C.
- *Boiling point* **(5.2.3) FB 5**: 1461 °C.
- *Relative density* **(5.2.5) FB 5**: 2.17 g/mL at 20 °C.

IDENTIFICATION

A. To 2 mL of *Solution (1)*, described below, add a few drops of concentrated sulphuric acid through the pipe walls. Partial cold decomposition and complete hot decomposition are observed, with chloride acid detachment, that can be recognized by the irritating odor and the production of white ammonium chloride clouds whenever a glass stick dampened with ammonium hydroxide is kept next to the tube spout.
  – *Solution (1)*: use solution of sodium chloride 0.1 *M*, prepared with recently purified water. The sodium chloride solution allows to perform the characterization reactions of sodium ion and chloride ion.

B. To 2 mL of *Solution (1)*, described in test **A.** for *Identification*, add a few drops of silver nitrate solution 0.1 *M*. It is observed the creation of a white silver chloride precipitate, insoluble in water and in diluted nitric acid, but soluble in ammonium hydroxide solution.

C. To 2 mL of *Solution (1)*, described in test **A.** for *Identification*, add a few drops of lead nitrate solution 0.1 *M* it is observed the creation of a white lead chloride precipitate.

D. Humidify platinum loop with *Solution (1)*, described in test **A.** for *Identification*, sour with chloride acid at 10% (v/v). Take it to the Bunsen burner flame reductive zone (non illuminating). It is observed non luminous intense yellow colored flame, which is not observed when interposed cobalt-blue glass slide.

This translation does not replace the portuguese version.

PURITY TESTS

- **Acidity or alkalinity.** Add five drops of bromothymol blue SI to 10 mL of *Solution (1),* described below.
  - *Solution (1)*: dissolve 10 g of the sample into purified water. Fill the volume to 100 mL with the same solvent. The solution must be clear.
- The indicator change must not require more than 0.2 mL of chloride acid solution 0.02 *M* for blue or green to yellow change or 0.1 mL of sodium hydroxide solution 0.02 *M* for yellow to blue change.
- **Barium.** To 5 mL of *Solution (1)*, described in *Acidity or alkalinity* test in *Purity tests*, add 1 mL of sulphuric acid solution *M* and to the other 5 mL of *Solution (1)* add 1 mL of purified water. Both solutions must remain equally clear after a 2 hour period.
- **Heavy metals (5.3.2.3) FB 5.** Use *Method I*. Proceed as described in *Limit test for heavy metals*. At most 0.0005% (5 ppm).
- **Bromide and iodide.** To 10 mL of *Solution (1)*, described *Acidity or alkalinity* test in *Purity tests*, add drop by drop and shaking, 5 mL of chloroform and 5 mL of water chloride SR. The chloroform must remain colorless, not being colored neither red-violet nor orange.
- **Sulfate.** To 10 mL of *Solution (1)*, described *Acidity or alkalinity* test in *Purity tests*, add 30 mL of purified water, 3 mL of hydrochloric acid 3 *M* and 1 mL of barium chloride 0,5 *M*. Fill the volume to 50 mL with purified water and heat in water bath for 10 minutes: if opalescence is observed, this must not be more intense than that produced by a solution prepared through the addition of 0.4 mg of sodium sulfate, 30 mL of purified water, 3 mL of hydrochloric acid 3 *M* and 1 mL of barium chloride 0,5 *M*. Fill the volume to 50 mL with purified water and heat in water bath for 10 minutes.

DOSAGE

- Dissolve approximately 0.1 g of salt, weighed with 1 mg accuracy, into 50 mL of purified water. Add 5 mL of nitric acid 6 *M*, 50 mL of silver nitrate 0,1 *M* SV and 1 mL of ammoniacal ferric sulfate solution at 40% (p/v). Carefully shake. Add 2 mL of nitrobenzene and titrate with potassium thiocyanate 0.1 *M* SV. The volume of silver nitrate which reacted with sodium chloride will be determined by the difference between the 50 mL added and the volume of thiocyanate spent in titration. Each mL of silver nitrate 0.1 *M* SV that reacted corresponds to 0.006 g of sodium chloride.

PACKAGING AND STORAGE

- In tightly closed neutral glass container.

DERIVED FORM

- **Starting point.** Sea sodium chloride (NaCl)
- **Inert ingredient.** Use ethanol at 30% (v/v) until 3 CH or 6 DH and for others, follow the general rule for preparing derived pharmaceutical forms.
- **Method.** *Hahnemannian method* **(11.1)**, *Korsakovian method* **(11.2)**, *Continuous flow method* **(11.3)**.
- **Dispensation.** From 1 CH or 1 DH, following dispensation general rule.
- **Packaging and storage.** In amber, tightly closed neutral glass container, protected from light and heat.

This translation does not replace the portuguese version.

NATRUM SULPHURICUM

- Na_2SO_4; 142,04 [*7757-82-6*]
- Contains at least 99.0%, at most 100.5% of Na_2SO_4 calculated in relation to the substance kiln-dried for two hours at 100 °C.

HOMEOPATHIC SYNONYMS
- Natrii sulfas anhidricus, Natrum sulphuratum, Natrum sulfuricum, Natrum sulfuricum siccum, Sodii sulphas, Sulfas sodicus, Natrium sulphuricum.

CHEMICAL NAME
- Anhydrous sodium sulfate.

DESCRIPTION
- **Physicochemical characters.** Moderately thin white powder, odorless, salty flavored and slightly bitter, hygroscopic.
- **Solubility.** Easily soluble in water, insoluble in ethanol, ethyl ether and chloroform.
- **Incompatibilities.** Calcium, strontium, barium, silver and lead soluble salts.

Physicochemical constants.
- *Fusion point* **(5.2.2) FB 5**. 888 °C.
- *Boiling point* **(5.2.3) FB 5**. Decompose over 890 °C.
- *Relative density* **(5.2.5) FB 5**. 2.70 g/ml at 20 °C.

IDENTIFICATION

A. Sulfate. To 5 mL of *Solution (1)*, described below, add 5 mL of barium chloride solution 0.1 *M*, it is observed the creation of a white barium sulfate precipitate insoluble in diluted hydrochloric acid and nitric acid.
- *Solution (1)*: dissolve 1 g of the sample into 10 mL of purified water.

B. Sodium. Humidify platinum loop with *Solution (1)*, described in *Sulfate* test, in *Identification*. Take it to the Bunsen burner flame reductive zone (non illuminating). It is observed non luminous intense yellow colored flame, which is not observed when interposed cobalt-blue glass slide.

PURITY TESTS
- **Acidity or alkalinity.** Add one drop of bromothymol blue SI to 10 mL of *Solution (1)*
  - *Solution (1)*: dissolve 2.2 g of the sample, into purified water and fill the volume to 100 mL.
  - It must not be necessary more than 0.5 mL of hydrochloric acid solution 0.01 *M* or sodium hydroxide solution 0.01 *M* for indicator's color changing.
- **Arsenic (5.3.2.5) FB 5.** 2.5 g of sodium sulfate must satisfy to *Arsenic limit test*. At most 0.001% (10 ppm).
- **Chloride (5.3.2.1) FB 5.** Dilute 5 mL of *Solution (1)*, described in *Acidity or alkalinity* test in *Purity tests*, until 15 mL volume with purified water. The solution must satisfy to *Chloride limit test*. At most 0.02% (200 ppm).

This translation does not replace the portuguese version.

DOSAGE

- Dissolve about 250 mg of the sample, weighed with 1 mg accuracy, into 250 mL of purified water. Add 10 mL of hydrochloric acid 2 *M*. heat until boiling and add sufficient amount of barium chloride solution 0,25 *M* until there is no more precipitation. Heat in water bath for 60 minutes, occasionally shaking. Collect the formed precipitate, filtering it through sintered plate glass funnel. Wash and dry the residue and then incinerate in a previously weighed crucible at 600 °C weigh the resulting residue: each residue gram corresponds to 0.608 g of Na_2SO_4.

PACKAGING AND STORAGE

- In amber, tightly closed neutral glass container.

DERIVED FORM

- **Starting point.** Anhydrous sodium sulfate (Na_2SO_4).
- **Inert ingredient.** Use lactose until 3 CH or 6 DH and for others, follow the general rule for preparing derived pharmaceutical forms.
- **Method.** *Hahnemannian method* **(11.1)**, *Korsakovian method* **(11.2)**, *Continuous flow method* **(11.3)**.
- **Dispensation.** From 1 CH or 1 DH, following dispensation general rule.
- **Packaging and storage.** In amber, tightly closed neutral glass container, protected from light and heat.

This translation does not replace the portuguese version.

NUX VOMICA

- *Strychnos nux vomica* (L.) – LOGANIACEAE

HOMEOPATHIC SYNONYMS
- Strychnos nux vomica, Strychnos colubrina, Colubrina, Noz vomica.

APPLIED PART
- Dry seeds.

PLANT DESCRIPTION
- *Strychnos nux vomica* L. is an evergreen tree with short thick, twisted, gray, irregularly branched and of smooth bark trunk. Its leaves are opposite, with short oval petioles containing three to five veins, shining and smooth in ventral and dorsal faces and measure from 4 cm to 10 cm in length by 2 cm to 5 cm in width. The flowers are small, white-greeny colored, disposed in end corymbs. The fruit is of round berry type, with 7 cm to 10 cm in diameter, shiny orange colored. When ripe, it becomes smooth and hard and contains gelatinous pulp in which there are found seeds in number ranging from 1 to 5. The seeds are discoid, flat and irregular, with 2 cm to 2.5 cm in diameter and 5 mm in thickness on average, concave-convex, being one of the margins more thicken, with a central depression; their color range from light gray to greeny gray, they are corneal and shiny.

DRUG DESCRIPTION
- The drug is constituted by dry seeds which have raised centrally positioned hilum, similar to a wart, linked to the micropyle through a prominent radial line.
- The transversely cut seed reveals silky, thin integument composed by piles of dilated lignified base and body curved over the surface, translucent, corneal, light gray colored ranging until pinky gray endosperm. The structure center contains a cavity that decreases from periphery to the center. The seed's tangential longitudinal section externally evinces slightly thick, gray colored integument, with corneal, translucent endosperm occupying the surface's major part. The embryo is small and appears on the external region of the endosperm adjacent to the micropyle. It may be observed the presence of two heart-shaped, smooth cotyledons, with five to seven veins and whity clubbed radicle.
- Seed's transversal sections reveal brown shade integument, constituted by well-developed spermoderm, formed by a cell line, where each cell forms a pile of about 1 mm in length, elbow folded, of dilated, sclerified base. Such base is similar to a brachiesclerite of reduced lumen and evident punctuations. The pile body, that is, the extension starting from the base is provided with filiform thickenings that anastomoses themselves extending until the vertex. Integument's internal part is formed by tangentially elongated, mashed cells.
- The endosperm is constituted by cells with quite the same diameter with hemicellulose strongly thicken walls. This cells reveal fat content droplet shaped, spherical or polyhedral aleurone grains with great globoids in same cases. The vascular bundle present in hilum region is smooth and characterized for spiral shaped vases.

This translation does not replace the portuguese version.

DRUG IDENTIFICATION

Note: *proceed the drug cut and put the obtained cuts in appropriate containers, covering them with petroleum ether. Shake for one minute. Transfer two out of such cuts to two blades for microscopy and proceed respectively in each one with the following Identification tests.*

A. Add over the cut one drop of ammonium vanadate solution at 1% (p/v) into sulphuric acid. It is observed the appearance of endosperm's red or reddish purple color due to the presence of strychnine.

B. Add to the second cut a drop of fumigant nitric acid. It is developed an orange color due the presence of brucine.

MOTHER-TINCTURE PREPARATION

- Proceed as described in *Preparation of plant origin mother-tincture* **(10.1)**. *Strychnos nux vomica*'s mother-tincture is prepared by maceration or percolation, so as the alcohol content during and at the end of the extraction is 65% (v/v). To reduce the seeds to dust, necessary precautions must be taken provided the drug's toxicity.

MOTHER-TINCTURE CHARACTERISTIC

- Yellowish brown colored liquid, with characteristic odor and bitter flavor.

IDENTIFICATION

A. To five drops of mother-tincture, add one drop of sulphuric acid at 10% (p/v) Evaporate until dry. It is observed the appearance of violet color.

B. Evaporate 1 mL of mother-tincture into boiling water bath. To the residue, add 0.5 mL of hydrochloric acid at 5% (v/v) followed by the addition of a few drops of potassium iodide mercury SR. It is observed the creation of a yellowish white precipitate.

C. Evaporate 1 mL of mother-tincture into boiling water bath. To the residue, add 0.5 mL of hydrochloric acid at 5% (v/v) followed by the addition of a few drops of potassium iodobismutate SR2. It is observed the slow creation of an orange precipitate.

D. Evaporate five drops of mother-tincture into boiling water bath. Allow it to cool. To the residue, add two drops of fumigant nitric acid. It is developed an orange red color.

E. Proceed as described in *Thin layer Chromatography* **(5.2.17.1) FB 5**, using silica-gel G as support and mixture of chloroform, methanol and ammonium hydroxide (95:5:1) as mobile phase. Apply separately to the plate 10 μL of mother-tincture and 10 μL of the recently prepared pattern solutions, describe as follows.
  - *Pattern Solution (1)*: dissolve 10 mg of strychnine into 10 mL of ethanol at 96% (v/v).
  - *Pattern Solution (2)*: dissolve 10 mg of brucine into 10 mL of ethanol at 96% (v/v).

- Develop the chromatogram for a course of 10 cm. Remove the plate, allow it to air dry. After, heat it in a stove at a temperature between 105 °C and 110 °C for 15 minutes. Allow it to cool. Nebulize it with potassium iodobismutate SR2 and examine it under natural light. Mother-tincture's chromatogram reveals two orange stains with the same Rf ratings corresponding to those of *Pattern Solution (1)* and of *Pattern Solution (2)*, respectively.

PURITY TESTS

- **Titration in ethanol.** Must range from 60% to 70% (v/v).
- **Dry residue.** Must be equal or higher than 1.0% (p/v).

This translation does not replace the portuguese version.

PACKAGING AND STORAGE

- In amber, tightly closed neutral glass container, protected from light and heat.

DERIVED FORM

- **Starting point.** Mother-tincture.
- **Inert ingredient.** From 1CH to 3CH or from 1CH to 6DH, use the same alcohol content as mother-tincture's. For the other applications, follow the general rule for preparing derived pharmaceutical forms.
- **Method.** *Hahnemannian method* **(11.1)**, *Korsakovian method* **(11.2)**, *Continuous flow method* **(11.3)**.
- **Dispensation.** From 1 CH or 2 DH, following dispensation general rule.
- **Packaging and storage.** In amber, tightly closed neutral glass container, protected from light and heat.

This translation does not replace the portuguese version.

PAEONIA OFFICINALIS

- *Paeonia officinalis* (L.) – RANUNCULACEAE

HOMEOPATHIC SYNONYMS
- Paeonia, Peonia, Paeonia peregrina, Rosa benedicta.

APPLIED PART
- Root.

PLANT DESCRIPTION
- *Paeonia officinalis* L. is a herbaceous plant with 60 cm to 70 cm in height, vivacious, with strong fasciculated roots, robust, of great, alternating, dark green colored leaves, shiny on the upper face and divided in elongated, oval, lobulated leaflets. It reveals great, lonely and terminal flower which has a chalyx with five herbaceous sepals and a corolla with five to ten reddish pink petals, with stamens of indefinite number and with two to five insulated, pluriovulated carpels. The root is fasciculated, with fusiform, thick dilations. It measures, on average, 15 cm in length, whilst its diameter may range from 5 mm to 15 mm. It is internally violish white colored and recovered with a dark cortex layer, slightly rough. Its transversal cut reveals cortical parenchyma of amylaceous nature; soft pericycle involving central cylinder with numerous radial striae, with the primary wood in the center part. Whenever fresh, the root emits strong, unpleasant odor; its taste is astringente and slightly bitter.

DRUG DESCRIPTION
- The drug reveals the macroscopical characters above described.

MOTHER-TINCTURE PREPARATION
- Proceed as described in *Preparation of plant origin mother-tincture* **(10.1)**. *Paeonia officinalis*'s mother-tincture is prepared by maceration or percolation, so as the alcohol content during and at the end of the extraction is 65% (v/v) according to the general technique for preparing mother-tincture.

MOTHER-TINCTURE CHARACTERISTICS
- Orange brown colored liquid, of characteristic aromatic odor and of spicy, earthy flavor.

IDENTIFICATION
A. To 1 mL of mother-tincture, add a few drops of ferric chloride at 10% (p/v). It is developed dark violet-blue color.

B. To 1 mL of mother-tincture, add 1 mL of alkaline cupric tartrate SR. Heat until boiling. It is observed the creation of an orange red precipitate.

C. To 1 mL of mother-tincture, add some crystals of resorcinol. Heat until boiling. It is developed red color.

D. To 1 mL of mother-tincture, add a few drops of Tollens reagent. It is observed cooled reduction, developing grayish brown color followed by the creation of a black precipitate. Heat until boiling. It is observed the creation of silver mirror.

E. Proceed as described in *Thin layer Chromatography* **(5.2.17.1) FB 5**, using silica-gel G as support and mixture of chloroform, ethyl acetate and anhydrous formic acid (50:40:10) as a mobile phase. Apply 30 μL of mother-tincture to the plate. Develop the chromatogram

This translation does not replace the portuguese version.

for a course of 10 cm. Remove the plate, allow it to air dry. Examine under ultraviolet light (365 nm). In general, it is observed one or two stains with brown fluorescence, relatively well separate and with Rf near 0.20, other with the same fluorescence and with Rf near 0.35, followed by two other, also with brown fluorescence, with approximate Rf ratings respectively at 0.50 and 0.70. There also can be detected one last stain with greenish fluorescence and with Rf near 0.95. After, nebulize the plate with recently prepared solution of solid blue salt B at 0.5% (p/v). Examine under natural light. The chromatogram reveals a pinky stain, with Rf near 0.35 and two others, orange, with Rf respectively near 0.50 and 0.70.

- Develop one more chromatogram using silica-gel G as support and mixture of ethyl acetat, anhydrous formic acid and purified water (80:10:10) as a mobile phase. Apply 30 μL of mother-tincture to the plate. Develop the chromatogram for a course of 10 cm. Remove the plate, allow it to air dry. After, nebulize the plate with vanillin phosphoric reagent, heat in stove at a temperature between 100ºC and 105 °C for 10 minutes. Examine under natural light. The chromatogram reveals a greenish brown colored stain with Rf near 0.10, another orange colored one with Rf near 0.20, and a third one, intense green colored with Rf near 0.45 and the last one, intense pink colored with Rf near 0.90.

PURITY TESTS

- **Titration in ethanol.** Must range from 60% to 70% (v/v).
- **Dry residue.** Must be equal or higher than 1.2% (p/v).

PACKAGING AND STORAGE

- In amber, tightly closed neutral glass container, protected from light and heat.

DERIVED FORM

- **Starting point.** Mother-tincture.
- **Inert ingredient.** From 1CH to 3CH or from 1CH to 6DH, use the same alcohol content as mother-tincture's. For the other applications, follow the general rule for preparing derived pharmaceutical forms.
- **Method.** *Hahnemannian method* **(11.1)**, *Korsakovian method* **(11.2)**, *Continuous flow method* **(11.3)**.
- **Dispensation.** From TM, following general rule of dispensation.
- **Packaging and storage.** In amber, tightly closed neutral glass container, protected from light and heat.

This translation does not replace the portuguese version.

PARREIRA BRAVA

- *Chondodendron tormentosum* Ruiz et Pavon – MENISPERNIACEAE

HOMEOPATHIC SYNONYMS
- Parreira Brava, Pareira Brava, Pareirae radix.

APPLIED PART
- Dry root.

PLANT DESCRIPTION
- *Chondodendron tormentosum*'s dry root is constituted of dark brown branched fragments, cylinder shaped, tortuous and strangled.
- Its dimension is variable and may achieve until 6 cm. Its surface is covered by easily detachable bark, revealing longitudinal grooves and transversal striae. Sectioned, it is revealed fibrous, fatty and reddish brown. It reveals a number of thick areas embedded into each other, generally starting from an eccentric point. On microscopical examination of a transversal section, it is successively observed: fairly thick black bark, barely developed cortical parenchyma containing some sclerose cells of punctuated, slightly thick cells, four to five lines of sclerenchymatic cells disposed in continuous rings of fairly thick, coniculed walls. It is also observed cuneiform vascular bundles, separate by long medullar rays constituted by compact fibers and fairly thick walls containing vases usually insulated and recovered by a phloem, a parenchymatous pericycle and by a lignified parenchyma. The central cylinder is formed by the superposition of sclerenchymatic cells around irregular eccentric rings and by phloem-woody bundles. The cortical parenchyma and the medullar rays contain starch.
- The drug is of weak odor and bitter flavor, strongly marked but momentary.

DRUG DESCRIPTION
- The drug reveals the macroscopical and microscopical characters above described.

MOTHER-TINCTURE PREPARATION
- Proceed as described in *Preparation of Mother-tincture from dry plants* **(10.1.1)**. *Chondodendron tormentosum*'s mother-tincture is prepared by maceration or percolation in ethanol at 65% (v/v) from the plant's dry root, according to the general technique for preparing mother-tincture.

MOTHER-TINCTURE CHARACTERISTICS
- Orange brown colored liquid, of weak odor and of intense bitter, unpleasant flavor.

IDENTIFICATION
A. To 2 mL of mother-tincture, add five drops of Tollens reagent. It is observed cooled reduction forming dark gray or black colored precipitate.
B. To 2 mL of mother-tincture, add one drop of ferric chloride solution at 10% (p/v). It is developed dark green color.
C. To 2 mL of mother-tincture, add one drop of the recently prepared mixture, formed by equal parts of ferric chloride solution at 1% (p/v) and potassium ferricyanide at 1% (p/v). It is developed dark green color.

This translation does not replace the portuguese version.

D. To 2 mL of mother-tincture, add five drops of silver nitrate solution at 1% (p/v). Heat in boiling water bath for one minute. It is observed partial reduction with development of dark brown color.
E. To 2 mL of mother-tincture, add 1 mL of purified water. It is observed slight turbidity.
F. To 2 mL of mother-tincture, add a few milligrams of powder zinc, followed by adding 0.5 mL of concentrated hydrochloric acid. The solution changes from reddish brown to greenish yellow.
G. Evaporate 2 mL of mother-tincture until dry. Treat the residue with 5 mL of hydrochloric acid at 5% (p/v). Filter, distribute the filtrate into two test tubes. To one of them, add two drops of potassium iodide and bismuth subnitrate SR, and to the other two drops of potassium iodide mercury SR. It is observed the creation of respectively orange and white precipitate.
H. Proceed as described in *Thin layer Chromatography* **(5.2.17.1) FB 5**, using silica-gel G as support and mixture of toluene, acetone, ethanol and ammonium hydroxide (15:20:6:2) as a mobile phase. Apply 20 μL of mother-tincture to the plate. Develop the chromatogram for a course of 10 cm. Examine under ultraviolet light (365 nm). The chromatogram generally reveals stain of yellow fluorescence and Rf rating near 0.10, another of greenish fluorescence and Rf near 0.50, another one of greenish yellow fluorescence and Rf near 0.60 and another of blue fluorescence and Rf near 0.80, and the last one, of greenish blue fluorescence and Rf near 0.95.
- At a second stage of the same chromatographic plate's revelation, nebulize it with potassium iodide and bismuth subnitrate SR. Observe it under visible light. There appears two orange stains with Rf near 0.50 and 0.60. It may also appear, over Rf 0.50, three to four other stains of orange color, lighter than the previous.

PURITY TESTS
- **Titration in ethanol.** Must range from 60% to 70% (v/v).
- **Dry residue.** Must be equal or higher than 0.8% (p/v).

PACKAGING AND STORAGE
- In tightly closed neutral glass containers.

DERIVED FORM
- **Starting point.** Mother-tincture.
- **Inert ingredient.** At the first three hundredth applications and first six decimal applications, use alcohol content equal to mother-tincture's.
- **Method.** *Hahnemannian method* **(11.1)**, *Korsakovian method* **(11.2)**, *Continuous flow method* **(11.3)**.
- **Dispensation.** From 1CH and 1DH, it will be applied ethanol with the same ethanol content as mother-tincture's, at first three applications for hundredth scale and first six application for decimal scale. From then, apply water-alcohol solution 30% (p/p).
- **Packaging and storage.** In amber, tightly closed neutral glass container, protected from light and heat.

This translation does not replace the portuguese version.

PHYTOLACCA DECANDRA

- *Phytolacca decandra* (L.) – PHYTOLACACCEAE

HOMEOPATHIC SYNONYMS
- Phytolacca americana, Phytolacca vulgaris, Blitum americanum.

APPLIED PART
- Root.

PLANT DESCRIPTION
- *Phytolacca decandra* L. herbaceous plant which achieve until 2 m in height, revealing great napiform roots, branches upright, round and without piles (glabrous), ramifying at apex's height. The leaves are light green, with 10 cm to 40 cm in height, short petioles; they are alterning, eliptic-oval, sharp, full, of smooth, wavy edges and glabrous. The inflorescence is constituted by a bunch of small flowers with five petaloid sepals, pinky white or greenish white containing ten stamens, one upper ovary with ten carpels together, short style. The fruits are berries of about 1 cm in diameter and, when ripe, characteristic dark purple colored.

DRUG DESCRIPTION
- The roots are odorless and have flavor initially earthy, mellow, becoming frankly bitter. They tend to have 1 cm to 3 cm in thickness, rarely achieving 8 cm. They are yellowish brown, rolled and curved. The young roots reveal strict central xylem, occupying a little more than 1/3 out of the diameter and whitish yellow peel. The olds roots reveal narrow additional xylem, yellowish, radial around the central part, which may be insulated or in several concentric circles.

MOTHER-TINCTURE PREPARATION
- Proceed as described in *Preparation of plant origin mother-tincture* **(10.1)**. *Phytolacca decandra*
- L.'s mother-tincture is prepared by maceration or percolation, so as the alcohol content during and at the end of the extraction is 60% (v/v) according to the general technique for preparing mother-tincture.

MOTHER-TINCTURE CHARACTERISTICS
- Pale yellow colored liquid with spicy flavor and slightly bitter.

IDENTIFICATION
A. To 1 mL of mother-tincture, add 1 mL of purified water. Vigorously shake it. It is observed development of abundant, persistent foam.
B. To 1 mL of mother-tincture, add one drop of ferric chloride solution at 10% (p/v). It is developed dark green color.
C. To 1 mL of mother-tincture, add two drops of recently obtained mixtured, formed by two equal parts of ferric chloride solution at 1% (p/v) and potassium ferricyanide at 1% (p/v). It is developed dark green color.
D. To 2 mL of mother-tincture, add five drops of Tollens reagent. Heat in boiling water bath for 1 minute. It is observed development of black precipitate.

This translation does not replace the portuguese version.

E. To 2 mL of mother-tincture, add five drops of alkaline cupric citrate SR. Heat in boiling water bath for 1 minute. It is observed development of orange precipitate.

F. Evaporate 5 mL of mother-tincture until dry. Treat the residue with 5 mL of hydrochloric acid at 5% (p/v). Filter. To the filtrate, add two drops of potassium iodobismutate SR2. It is observed development of orange precipitate.

G. Observe 1 mL of mother-tincture under ultraviolet light (365 nm). It is observed blue fluorescence. Dilute the test pipe content with 10 mL of purified water. Observe under ultraviolet light (365 nm). The fluorescence persists.

H. To 2 mL of mother-tincture, add about 0.1 g of sucrose. Shake it until complete dissolution. After, add five drops of concentrated sulphuric acid. Heat in boiling water bath for 1 minute. It is developed dark brown color.

I. To 1 mL of mother-tincture, add 2 mL of purified water. It is observed light yellow opalescence.

J. To 1 mL of heated mother-tincture, add 1 mL of hydrochloric acid at 1% (p/v). It is developed intense red color.

K. Proceed as described in *Thin layer Chromatography* **(5.2.17.1) FB 5**, using mixture of ethyl acetate,ethylmethylketone, purified water and anhydrous formic acid (50:30:20:10) as a mobile phase. Apply 30 μL of mother-tincture to the plate. Develop the chromatogram for a course of 10 cm. Remove the plate, allow it to air dry. Examine under ultraviolet light (365 nm). The chromatogram generally reveals brown colored stain with Rf near 0.40, another one of orange yellow fluorescence with Rf near 0.50, a third one of pale yellow fluorescence with Rf near 0.65, other of yellow fluorescence with Rf near 0.75 and two others, virtually superposed, being one of blue fluorescence and other red, both together with the solvent line. After, nebulize the plate with aminoethanol diphenyl borate at 1% (p/v). Examine under ultraviolet light (365 nm). The chromatogram reveals a stain of orange fluorescence and Rf near 0.40, two others of yellow fluorescence with Rf ratings near 0.50 and 0.70.

- Develop one more chromatogram with the same conditions as the previous one. Nebulize the plate with antimony chloride at 20% (p/v) in chloroform. Examine under ultraviolet light (365 nm). The chromatogram reveals two stains of greenish yellow fluorescence with Rf ratings near 0.25 and 0.40 and two others of green fluorescence with Rf value near 0.50 and 0.25.

PURITY TESTS

- **Titration in ethanol.** Must range from 55% to 65% (v/v).
- **Dry residue.** Must range from 2.2% to 3.5% (p/v).

PACKAGING AND STORAGE

- In amber, tightly closed neutral glass container, protected from light and heat.

DERIVED FORM

- **Starting point.** Mother-tincture.
- **Inert ingredient.** From 1CH to 3CH or from 1CH to 6DH, use the same alcohol content as mother-tincture's. For the other applications, follow the general rule for preparing derived pharmaceutical forms.
- **Method.** *Hahnemannian method* **(11.1)**, *Korsakovian method* **(11.2)**, *Continuous flow method* **(11.3)**.
- **Dispensation.** From 1 CH or 1 DH, following dispensation general rule.
- **Packaging and storage.** In amber, tightly closed neutral glass container, protected from light and heat.

This translation does not replace the portuguese version.

RHUS TOXICODENDRON

- *Rhus toxicodendron* (L.) – ANACARDIACEAE

HOMEOPATHIC SYNONYMS
- Rhus, Rhus humile, Rhus pubescens, Rhus radicans, Rhus verrugosa, Vitis canadensis.

APPLIED PART
- Leaves.

PLANT DESCRIPTION
- Deciduous shrub with pinky, branched stem which measures from 30 cm to 100 cm in height. Alternating, great, deciduous, composed and imparipinnate leaves, with unequal side leaflets in the base and sessile. The terminal is longer at common petiole's expansion end, rombicovate, sharp with diverse or full erasures, lobulated, pubescent. The leaves' characteristics range depending on the proximity of the object supporting the plant. It is a polygamous species with small greenish white flowers. The plant contains yellowish brown latex, acre, with penetrating and nasty odor, extremely toxic and that darken whenever exposed to air.

MICROSCOPICAL DESCRIPTION
- The epidermises are formed by sinuous wavy cells and only the bottom one reveals stomata. The mesophile consists of one palisade layer, one accumulated layer of conic cells and one spongy tissue of branched cells over a level. Within palisade layer, it is abundantly found huge insulated oxalate crystals, and through the rest of mesophile, numerous druses. The vascular accessories' leptoma is accompanied of lactiferous ducts. The villus is formed by smooth piles, of thick wall, from six to eight cells, by claviform glandular piles, with pedicle of one or several cells and gland of one to three cells.

DRUG DESCRIPTION
- The drug reveals the macroscopical and microscopical characters above described.

MOTHER-TINCTURE PREPARATION
- Proceed as described in *Preparation of plant origin mother-tincture* **(10.1)**. *Rhus toxicodendron* L.'s mother-tincture is prepared by maceration or percolation, so as the alcohol content during and at the end of the extraction is 65% (v/v) according to the general technique for preparing mother-tincture.

MOTHER-TINCTURE CHARACTERISTIC
- Greenish colored, spicy flavor and herbaceous odor liquid.

IDENTIFICATION
A. To 1 mL of mother-tincture, add a few drops of ferric chloride at 10% (p/v). It is developed black color.
B. To 1 mL of mother-tincture, add 1 mL of concentrated hydrochloric acid and one fragment of magnesium or metalic zinc. It is observed the appearance of reddish color.
C. To 1 mL of mother-tincture, add 1 mL of alkaline cupric citrate SR and heat until boiling. It is observed the development of reddish precipitate.

This translation does not replace the portuguese version.

D. To 1 mL of mother-tincture, add one lentil of potassium hydroxide. After its dissolution, shake with 2 mL of 1-butanol and separate the organic part. Evaporate in water bath. Add to the residue a few milligrams of *p*-dimethylaminobenzaldehyde, three drops of concentrated sulphuric acid and 1 mL of purified water. It is developed violish red color.

E. Proceed as described in *Thin layer Chromatography* **(5.2.17.1) FB 5**, using silica-gel G as support and mixture of chloroform, glacial acetic acid, methanol and water (15:8:3:2) as a mobile phase. Apply 20 μL of mother-tincture to the plate. Develop the chromatogram for a course of 10 cm. Remove the plate, allow it to air dry. Examine under ultraviolet light (365 nm). It is observed stain with brown fluorescence with Rf near 0.05 and another with blue fluorescence and Rf near 0.20, two brownish stains with Rf near 0.35 and 0.50, stain of yellow fluorescence and Rf near 0.60, one stain of brown fluorescence with Rf near 0.75 and one stain of red fluorescence and Rf near 0.95. After, nebulize the chromatogram with aminoethanol diphenyl borate solution at 1% (p/v) and examine under ultraviolet light. The chromatogram reveals two fluorescent blue stains with Rf ratings near 0.05 and 0.20, two fluorescent orange staing with Rf ratings near 0.35 and 0.50, one fluorescent yellow stain with Rf near 0.60 and one fluorescent blue stain superposed to a fluorescent yellow stain with Rf near 0.75.

PURITY TESTS

- **Titration in ethanol.** Must range from 60% to 70% (v/v).
- **Dry residue.** Must be equal or higher than 1.25% (p/v).

PACKAGING AND STORAGE

- In amber, tightly closed neutral glass container, protected from light and heat.

DERIVED FORM

- **Starting point.** Mother-tincture.
- **Inert ingredient.** From 1CH to 3CH or from 1CH to 6DH, use the same alcohol content as mother-tincture's. For the other applications, follow the general rule for preparing derived pharmaceutical forms.
- **Method.** *Hahnemannian method* **(11.1)**, *Korsakovian method* **(11.2)**, *Continuous flow method* **(11.3)**.
- **Dispensation.** From 1 CH or 2 DH, following dispensation general rule.
- **Packaging and storage.** In amber, tightly closed neutral glass container, protected from light

This translation does not replace the portuguese version.

RICINUS COMMUNIS

- *Ricinus communis* (L.) – EUPHORBIACEAE

HOMEOPATHIC SYNONYMS
- Ricinus, Ricinus virilis, Ricinus inermes, R. laevis, R. lividus.

APPLIED PART
- Ripe, dry seeds.

PLANT DESCRIPTION
- Shrubby, fairly branched plant, with thick stems, glabrous, fistulous, with prominent knotts, light green or purple colored, measuring from 2 m to 2 m in height. The leaves are simple, alternating, with fleshy, long, thick petiole, of palmed blade, with up to 45 cm in diameter, with five to ten great lobs of acute apex and jagged margins, bluish green colored. The inflorescences are terminal or axillary, pyramidal, forming long bunches with 20 cm to 30 cm in length; reveal light yellow flowers, they are unisex, disposed in sub-paniculate racemes and simple perianth. The male flowers are located at the top of the inflorescence and the females, at their bottom. The male flowers reveal membranous calyx, several stamens, whilst the females reveal deciduous calyx, three segment ovaries, entire styles and lonely ovums in each cell. The fruits are roughly globular, with orbicular outlines, green or bluish green colored, with glabrous surface. Each fruit encases three seeds. The seeds are elliptical, oval outlined, measuring from 9 mm to 12 mm in length by 7 mm to 8 mm in width and 5 mm to 8 mm in thickness; they are convex at dorsal face and generally flattened at ventral face, with round base. They are smooth, shiny, brown or reddish brown colored, striated, revealing stains that form drawings with different tones ranging from brownish to black, oily, of sweet, slightly acre flavor.

DRUG DESCRIPTION
- The drug reveals the macroscopical characters above described.

MOTHER-TINCTURE PREPARATION
- Proceed as described in *Preparation of plant origin mother-tincture* **(10.1)**. *Ricinus communis* L.'s mother-tincture is prepared by maceration or percolation, so the alcoholic content during and at the end of the extraction is 90% (v/v), according to the general technique of preparing mother-tincture.

MOTHER-TINCTURE CHARACTERISTICS
- Pale yellow colored liquid, of slightly intense odor and practically tasteless.

IDENTIFICATION
A. To 1 mL of mother-tincture, add 1 mL of purified water. Shake it. It is observed the appearance of milky turbidity.

B. Add 2 mL of mother-tincture into a test tube. Add 1 mL of Tollens reagent. It is developed dark brown color. After, heat it in boiling water bath for about 1 minute. Leave it for a few seconds. It is observed the creation of black precipitate.

C. Add 1 mL of mother-tincture into a test tube. After, add 10 drops of ninhydrin solution at 1% (p/v). Heat it in boiling water bath for about 1 minute. It is developed violet color.

This translation does not replace the portuguese version.

D. Add 1 mL of mother-tincture into a test tube. After, add 10 drops of recently formed reagent by equal parts of ferric chloride at 1% (p/v) and potassium ferricyanide at 1% (p/v). It is developed yellowish green color.

E. Proceed as described in *Thin layer chromatography* **(5.2.17.1) FB 5**, using silica-gel G as support and mixture of chloroform, acetone and glacial acetic acid (95:4:1) as a mobile phase. Add 10 μL of mother-tincture to the plate. Develop the chromatogram for a course of 10 cm. Remove the plate, let it air dry. Nebulize the plate with anisic aldehyde solution at 0.5% (v/v) and heat in stove at a temperature between 100ºC and 105 °C for 10 minutes. It is observed under visible light one to two violet stains with Rf near 0.25, two others, red, with Rf rangings near 0.40 and 0.55, which quickly changes to green color, an a fifth stain, violish pinky with Rf value near 0.70.

- Develop one more chromatogram at the same previous conditions. Nebulize the plate with potassium iodobismutate SR2. Examine under natural light. It is observed two orange stains with Rf values ranging from 0.40 to 0.55.

PURITY TESTS

- **Titration in ethanol.** Must range from 85% to 95% (v/v).
- **Dry residue.** Must be higher than 1.5% (p/v).

PACKAGING AND STORAGE

- In neutral glass, amber, tightly close container, protected from light and heat.

DERIVED FORM

- **Starting point.** Mother-tincture.
- **Inert ingredient.** From 1CH until 3Ch or 1DH until 6DH, use the same alcohol content of mother-tincture's. For the other applications, follow the general rule for preparing derived pharmaceutical forms.
- **Method.** *Hahnemannian Method* **(11.1)**, *Korsakovian Method* **(11.2)**, *Continuous flow method* **(11.3)**.
- **Dispensation.** From 1 CH or 1 DH, following dispensation general rule.
- **Packaging and storage.** In neutral glass, amber, tightly close bottle, protected from light and heat.

This translation does not replace the portuguese version.

RUTA GRAVEOLENS

- *Ruta graveolens* (L.) – RUTACEAE

HOMEOPATHIC SYNONYMS
- Ruta hortensis, Ruta latifolia, Ruta sativa, Ruta vulgaris.

APPLIED PART
- Entire plant.

PLANT DESCRIPTION
- *Ruta graveolens* L. is an evergreen shrub, with several 60 cm stems, fairly branched and thin. The 12 mm to 15 mm in length leaves are alternating with long petioles and fairly divided. The leaflets are oblong and the terminals are oval shaped, the top leaves are pinnate, of triangular outline, obtusecrenate, sub-coriaceous, greenish blue colored. The flowers are yellow, in terminal corymbs, over subdivided peduncles. Every part of the plant is full of transparent points, and the leaves covered by small glands which contain oil with peculiar balsamic odor.
- The epidermises contain small quantity of stomata at the top part and their major part at the foliar segments' base. The top epidermis' cells have slightly wavy or rectilinear outline, and the bottom, fairly sinuous. The mesophile is formed by two palisate layers, fluffy, of fairly large and short cells with spongy parenchyma, the bottom layer of which once again approximate the palisate shape. In mesophile, there are oxalate druses. It is observed numerous and huge schizolisigene storages that reach the epidermis. The four epidermical cells which cover them generally have rhombic shape and are fused underneath the others' level and they are glabrous.

DRUG DESCRIPTION
- The drug reveals the characters above described.

MOTHER-TINCTURE PREPARATION
- Proceed as described in *Preparation of plant origin mother-tincture* **(10.1)**. *Ruta graveolens* L.'s mother-tincture is prepared by maceration or percolation, so the alcoholic content during and at the end of the extraction is 65% (v/v), according to the general technique of preparing mother-tincture.

MOTHER-TINCTURE CHARACTERISTICS
- Greenish brown colored liquid, with strong odor and slightly bitter flavor.

IDENTIFICATION
A. To 2 mL of mother-tincture, add a few drops of ferric chloride solution at 10% (p/v). It is developed greenish brownish color.
B. To 1 mL of mother-tincture, add 1 mL of alkaline cupric citrate SR and heat until boiling. It is observed the creation of red precipitate.
C. To 1 mL of mother-tincture, add one fragment of magnesium or metalic and add 1 mL of hydrochloric acid at 5% (v/v). It is developed red color.
D. To 1 mL of mother-tincture, add one lentil of potassium hydroxide shaking it until its dissolution. After, by shaking, add 2 mL of isopropyl alcohol. Separate the organic

phase, evaporating it in water bath. To the residue thus obtained, add some crystals of *p*-dimethylaminobenzaldehyde, three drops of concentrated sulphuric acid and 1 mL of purified water. It is developed violish red color.

E. Proceed as described in *Thin layer chromatography* **(5.2.17.1) FB 5**, using silica-gel G as support and mixture of 1-butanol, glacial acetic acid and water (4:1:1). Add 20 μL of mother-tincture to the plate. Develop the chromatogram for a course of 10 cm. Remove the plate, let it air dry. Examine under ultraviolet light (365 nm). It will be observed fluorescent light yellow colored stain with Rf near 0.40, one fluorescent dark brown colored stain with Rf near 0.50 and over them, two stains, one fluorescent violish blue colored and another of greenish blue fluorescence, two fluorescent blue stains with Rf near 0.80 and one fluorescent violish colored stain with Rf near 0.95. Nebulize the chromatogram with antimony chloride solution at 20% (p/v) in chloroform. Examine under natural light. The chromatogram reveals one intense yellow colored stain with Rf near 0.50 and two other superposed stains, one green colored and another violish colored with Rf near 0.95.

- Develop one more chromatogram at the same previous conditions. Nebulize the plate with potassium iodobismutate SR2 and examine under natural light. The chromatogram reveals one or two orange stains with Rf near 0.50. It may also reveal one or two orange stains with Rf over 0.80.
- Develop one more chromatogram at the same previous conditions. Nebulize the plate with anisic aldehyde solution, heat it in stove at a temperature between 100ºC and 105 °C for 5 minutes. Examine under natural light. The chromatogram reveals one yellow brownish colored stain with Rf near 0.50, several violish colored stains with Rf ranging from 0.70 to 0.80 and two superposed violish colored stains with Rf near 0.95.

PURITY TESTS

- **Titration in ethanol.** Must range from 60% to 70% (v/v).
- **Dry residue.** Must be equal or higher than 1.5% (p/v).

PACKAGING AND STORAGE

- In neutral glass, amber, tightly close container, protected from light and heat.

DERIVED FORM

- **Starting point.** Mother-tincture.
- **Inert ingredient.** From 1CH until 3Ch or 1DH until 6DH, use the same alcohol content of mother-tincture's. For the other applications, follow the general rule for preparing derived pharmaceutical forms.
- **Method.** *Hahnemannian Method* **(11.1)**, *Korsakovian Method* **(11.2)**, *Continuous flow method* **(11.3)**.
- **Dispensation.** From 1 CH or 2 DH, following dispensation general rule.
- **Packaging and storage.** In neutral glass, amber, tightly close container, protected from light and heat.

This translation does not replace the portuguese version.

STAPHYSAGRIA

- *Delphinium staphysagria* (L.) – RANUNCULACEAE

HOMEOPATHIC SYNONYMS
- Staphisagria, Delphinium staphisagria, Staphydis agria, Staphydis pedicularis, Staphydis macrocarpa.

APPLIED PART
- Seeds.

PLANT DESCRIPTION
- *Delphinium staphysagria* L. is a herbaceous, biennial, robust plant, achieving 1 m to 1.5 m in height, pubescent, of erect, branching, green stem with purplish stains. Its leaves are alternating, petiolated, of smashed blade with lanceolate, entire or cleft segments. The blue flowers are disposed in irregular bunches, with five petaloid sepals, being that top extended in a short spur, smaller than the sepals, and the other ones sub-equal and deciduous. The corolla is formed by four free petals, being the two top extended in spur, this included in calyx, which also reveals two small side petals, with no spurs. The stamens are numerous. The fruit is constituted by three leaflets, intumesced, with about 2 cm in length, they are pubescent and contain four to five seeds, on average, which are compressed between themselves so as to appear only one oval shaped.

DRUG DESCRIPTION
- The drug is constituted by seeds angular, irregularly tetrahedral, whet at one of the ends and garbled at the others, with external surface reticulate and earthy colored. Internally, it is observed oily, white or yellowish albumen, developed, with a small embryo at the seed's most prominent end. It has slightly pronounced but unpleasant odor and its flavor is acre, fairly bitter, nasty, making the tongue tingle and whenever smashed, exhales intense and deeply unpleasant odor.
- Microscopically, it is observed the integument's external layer formed by unequal cells line which regularly protrude to the outside. Its walls are thick and full of small protrusions. There are several flattened cells' layers belonging to the middle internal integument, being the last one formed by minor elements and of thicker walls. The albumen is distinguished as reveals polygonal, great cells, containing oil and aleurone.

DRUG IDENTIFICATION

A. To 1 mL of *Solution (1)*, describe below, add 0.5 mL of sodium hydroxide at 10% (p/v). It is developed intense yellow color and turbidity.
  – *Solution (1)*: to 1 g of finally divided drug, add 10 mL of ethanol at 90%)v/v) and heat under reflux for 15 minutes. Allow it to cool. Filter.

B. In a watch glass, add 2 mL of *Solution (1)*, described in test **A.** of *Drug identification*. Evaporate it until obtaining solid residue. Add to the residue 1 mL of hydrochloric acid at 10% (v/v) and after, a few drops of potassium iodide mercury SR. It is observed the creation of white precipitate.

- Repeat the reaction described in test **B.** of *Drug identification* substituting the potassium iodide mercury SR for potassium iodobismutate SR2. It is observed the creation of orange precipitate.

This translation does not replace the portuguese version.

MOTHER-TINCTURE PREPARATION

- Proceed as described in *Preparation of plant origin mother-tincture* **(10.1)**. *Delphinium staphysagria* L.'s mother-tincture is prepared by maceration or percolation, so the alcoholic content during and at the end of the extraction is 65% (v/v), according to the general technique of preparing mother-tincture.

MOTHER-TINCTURE CHARACTERISTICS

- Pale yellow colored liquid, of slightly rancid odor, bitter flavor.

MOTHER-TINCTURE IDENTIFICATION

A. To 1 mL of mother-tincture, add 1 mL of purified water. It is observed milky turbidity.

B. To 1 mL of mother-tincture, add 0.5 mL of sodium hydroxide solution at 10% (p/v). Shake it. It is observed the creation of two phases, and the bottom one assumes lemon yellow color.

C. In watch glass, add 2 mL of mother-tincture and allow it to evaporate in boiling water bath, until dry. Add to the formed residue 1 mL of hydrochloric acid at 10% (v/v) and after, add a few drops of potassium iodide mercury SR. It is observed the creation of white precipitate.

D. Repeat the reaction described in test **C.** of *Identification* substituting the potassium iodide mercury SR for potassium iodobismutate SR2. It is observed the creation of orange precipitate.

E. Proceed as described in *Thin layer chromatography* **(5.2.17.1) FB 5**, using silica-gel G as support and mixture of 1-butanol, glacial acetic acid and purified water (40:10:10) as a mobile phase. Add 30 μL of mother-tincture to the plate. Develop the chromatogram for a course of 10 cm. Remove the plate, let it air dry. Examine under ultraviolet light (365 nm). The chromatogram generally reveals several fluorescent blue stains with Rf ranging from 0.20 and 0.80 and another, of greenish blue fluorescence at the height of the line achieve by the mobile phase.

- Develop one more chromatogram using silica- gel G as support and mixture of toluene, acetone, ethanol and concentrated ammonium hydroxide (45:45:7:3) as a mobile phase. Apply to the plate 40 µL of recently prepared *Sample solution*, described as follows.
  - *Sample solution*: evaporate 20 mL of mother-tincture until obtaining a volume of about 2 mL, after, add to it 10 mL of sulphuric acid at 1% (p/v). Filter. Alkalinize the filtrate with sufficient amount of concentrado ammonium hydroxide. Extract the solution thus obtained for two consecutive times, with 15 mL of chloroform, combining the products resulting of the two extractions in a bottle containing sufficient amount of anhydrous sodium sulfate. Shake it. After about 15 minutes, at rest, filter and evaporate in boiling water bath the extract totality until obtaining the residue which will be, after, dissolved with 1 mL of ethanol at 90% (v/v).
- Develop the chromatogram for a course of 10 cm. Remove the plate, let it air dry. Nebulize the plate with diluted potassium iodobismutate SR2. Examine under natural light. The chromatogram reveals a succession of orange stains with Rf between 0.30 and 0.90, being more evident four stains respectively with Rf values near 0.35, 0.65, 0.80 and 0.90.

PURITY TESTS

- **Titration in ethanol.** Must range from 60% to 70% (v/v).
- **Dry residue.** Must be equal or higher than 0.3%. (p/v).

PACKAGING AND STORAGE

- In neutral glass, amber, tightly close container, protected from light and heat.

This translation does not replace the portuguese version.

DERIVED FORM

- **Starting point.** Mother-tincture.
- **Inert ingredient.** From 1CH until 3Ch or 1DH until 6DH, use the same alcohol content of mother-tincture's. For the other applications, follow the general rule for preparing derived pharmaceutical forms.
- **Method.** *Hahnemannian Method* **(11.1)**, *Korsakovian Method* **(11.2)**, *Continuous flow method* **(11.3)**.
- **Dispensation.** From 2 CH or 4 DH, following dispensation general rule.
- **Packaging and storage.** In neutral glass, amber, tightly close container, protected from light and heat.

This translation does not replace the portuguese version.

SULPHUR

- S; 32,06 [*7704-34-9*]
- It contains at least 99% and at most the equivalent to 101% of S, in relation to dry substance.

HOMEOPATHIC SYNONYMS
- Sulphur sublimatum lotum, Sulphur lotum, Sulphur depuratum, Sulfur.

CHEMICAL NAME
- Sulfur.

DESCRIPTION
- **Physical characteristics.** Thin powder, lime yellow, tasteless and of characteristic odor.
- **Solubility.** Insoluble in water, slightly soluble in ethanol, soluble in carbon disulfide and in olive oil.
- **Incompatibilities.** Picric acid, chlorates, nitrates, potassium carbonate, metals, salts and metallic compounds in general, bismuth subnitrate, nitric acid, alkaline persulfates, peroxides and alkaline permanganates.

Physicochemical constants.
- *Relative density* **(5.2.5) FB 5**: about 2.06.
- *Fusion range* **(5.2.2) FB 5**: 118 °C to 120 °C**.**

IDENTIFICATION

A. The sublimate, washed sulfur burns with a small bluish flame exhaling sulphuric dioxide of characteristic odor.

B. To 0.1 g of the sample, add 5 mL of bromine water SR. Allow it to boiling keeping it until complete solution discoloring. Filter. To 2 mL of filtrate, add 1 mL of hydrochloric acid at 1% (v/v) and 1 mL of barium chloride solution at 1% (p/v). It is observed the creation of white precipitate.

PURITY TESTS
- **Solution aspect.** Shake 5 g of the sample with 50 mL of previously heated and cooled purified water. Leave it and filtrate. The solution is colorless **(5.2.12) FB 5**.
- **Acidity.** To 5 mL of solution described in *Solution aspect*, add 0.5 mL of phenolphtalein SI. For indicator's change it must not be necessary more than 0.2 mL of sodium hydroxide solution 0.01 *M*. Add 0.3 mL of hydrochloric acid solution 0,01 *M*. It is observed solution discoloring.
- **Arsenic (5.3.2.5) FB 5.** Shake it for 1 hour, 2.5 g of sulfur with 50 mL of ammonium hydroxide at 10% (v/v) and filter. Evaporate 25 mL of filtrate until dry. To the residue, add 2 mL of purified water and 3 mL of nitric acid at 10% (v/v). Evaporate the soution in boiling water bath until dry. The residue must satisfy *Arsenic limit test*. At most 0.0008% (8 ppm).
- **Chlorides (5.3.2.1) FB 5.** Dilute in purified water 6.25 mL of solution described in *Solution aspect*, until the volume of 15 mL. The solution must satisfy *Chloride limit test*. At most 0.008% (80 ppm).
- **Sulfates (5.3.2.2) FB 5.** With 15 mL of solution described in *Solution aspect*, proceed as described in *Sulfate limit test*. At most 0.01% (100 ppm).

This translation does not replace the portuguese version.

- **Loss for desiccation (5.2.9) FB 5.** Determine in 1 g of the heated sample for two hours in stove at a temperature between 100 °C and 105 °C shall lose at most 1% of its mass.
- **Calcination residue.** Determine in 2 g of the sample submitted to calcination at 800 °C shall reveal residue lower than 0.1%.

DOSAGE

- With 1 mg accuracy, weigh 1 g of sulfur previously dried in vacuum desiccator, over sulfuric acid, for 4 hours. Add 50 mL of potassium hydroxide *M* in ethanol at 96% (v/v). Heat the mixture until all the sulfur is dissolved. Add purified water until complete the volume of 250 mL. Transfer exactly 25 mL for 400 mL beaker, add 50 mL of hydrogen peroxide at 3% (p/v) and heat it in water bath for 1 hour. After, acidify with sufficient qualirt of hydrochloric acid at 10% (v/v), thereupon adding 200 mL of purified water. Heat it until boiling. Add, drop by drop, barium chloride at 12% (p/v) dissolved in purified water until there is no more precipitation. Heat the mixture in water bath for 1 hour. After, filter it through filtrating crucible of thin porosity, previously calcinated at 800 °C and after cooling, weighed. Transfer all the precipitate for the crucible and wash it first with hot water and then with ethanol.
- After, calcinate the crucible with the precipitate at a temperature of 600 °C for 1 hour. After cooling in desiccator, weigh the crucible and calculate the obtained precipitate's mass. The obtained mass of barium sulfate multiplied by 0.1374 represents the quantity of sulfur in the sample.

PACKAGING AND STORAGE

- In tightly closed container.

DERIVED FORMS

- **Starting point.** Washed and sublimated sulfur (S).
- **Inert ingredient.** Use lactose until 3 CH or 6 DH and for others, follow the general rule for preparing derived pharmaceutical forms.
- **Method.** *Hahnemannian Method* **(11.1)**, *Korsakovian Method* **(11.2)**, *Continuous flow method* **(11.3)**.
- **Dispensation.** From 1 CH or 1 DH, following dispensation general rule.
- **Packaging and storage.** In neutral glass recipient, amber, tightly closed.

This translation does not replace the portuguese version.

TARAXACUM OFFICINALE

- *Taraxacum dens leonis* Desf. – COMPOSITAE (ASTERACEAE)

HOMEOPATHIC SYNONYMS
- Taraxacum, Dens leonis, Lactuca pratense, Leontodontis, Leontodon officinale, Leontodon taraxacum, Leontodon vulgare, Taraxacum vulgare.

APPLIED PART
- Entire, blooming plant.

PLANT DESCRIPTION
- *Taraxacum dens leonis* Desf. is a herbaceous, perennial plant, with height ranging from 5 cm to 30 cm, annual, with penroot. The leaves are simple, grouped in rosette at the plant base, with no petiole, oblong or oval-oblong, with green blade, short-hairy or glabrous, entire, irregular pinatifid or pinatipartite, forming acute triangular lobesin both sides of the vein. The leaves' length may achieve 25 cm. The inflorescence is given in lonely chapters, located at hollow floral stems, pubescent, with 20 cm to 30 cm in height. Each chapter measures from 2 cm to 5 cm in diameter. The flowers are yellow, hermaphrodite, irregular. The androecium is formed by five equal, concrescent stamina. The anthers are apendicular at their end. The ovary is bottom, unilocular, constituted by two concrescent capels forming only one ovule which becomes achene. The achenes are fusiform or oblanceolate, compressed, frequently longitudinally curved, containing at one of the ends an agglomerate of piles which ease the flotation.

DRUG DESCRIPTION
- The drug reveals the macroscopical characters above described.

MOTHER-TINCTURE PREPARATION
- Proceed as described in *Preparation of plant origin mother-tincture* **(10.1)**. *Taraxacum officinale*'s mother-tincture is prepared by maceration or percolation, so the alcoholic content during and at the end of the extraction is 45% (v/v), according to the general technique of preparing mother-tincture.

MOTHER-TINCTURE CHARACTERISTICS
- Orange brown colored liquid, of unpleasant odor and sweet flavor.

IDENTIFICATION
A. To 2 mL of mother-tincture, in test tube, add five drops of timol ethanolic solution at 5% (p/v). Through the slightly inclined tube's walls, slowly add 1 mL of concentrated sulfuric acid. It is observed the creation of a red ring in separation surface, which quickly darken, turning reddish brown. After, shake the tube. It is then observed red color in all of the tube content.

B. To 1 mL of mother-tincture, add 5 mL of purified water and one drop of sodium hydroxide solution at 10% (p/v). It is developed yellow color. While shaking the tube, it shall be observed the creation of abundat foam.

This translation does not replace the portuguese version.

C. Add 2 mL of mother-tincture into a test tube. Add 1 mL of alkaline cupric citrate SR. After, heat it in boiling water bath for about 1 minute. It is observed the creation of orange precipitate.

D. Add 1 mL of mother-tincture into a test tube. After, add 10 drops of recently formed reagent by equal parts of ferric chloride at 1% (p/v) and potassium ferricyanide at 1% (p/v). It is developed dark green color.

E. Add 2 mL of mother-tincture into a test tube. After, add 1 mL of Tollens reagent. After rest, it is developed black color with the creation of precipitate. After, heat it in boiling water bath for about 1 minute. It is observed increase of the black precipitate.

F. Add 1 mL of mother-tincture into a test tube. Add 10 drops of ninhydrin at 1% (p/v) in ethanol at 90% (v/v). After, heat it in boiling water bath for about 1 minute. It is developed violish red color.

G. Add 1 mL of mother-tincture into a test tube. Add 10 drops of picric acid at 1% (p/v). Shake the tube. It is observed the intensification of the mother-tincture's color. Leave it for a few seconds. It is observed the separation of two phases, being the top light yellow and the bottom reddish orange.

H. Proceed as described in *Thin layer chromatography* **(5.2.17.1) FB 5**, using silica-gel G as support and mixture of ethyl acetate, anhydrous formic acid and purified water (80:10:10) as a mobile phase. Separately, apply to 20 µL of mother-tincture to the plate and 10 µL of recently prepared *Pattern solution*, described as follows.

– *Pattern solution*: luteolin solution at 10% (p/v) in ethanol at 96% (v/v).

- Develop the chromatogram for a course of 10 cm. Remove the plate, let it air dry. Examine under ultraviolet light (365 nm). The luteolin solution reveals brown stain with Rf near 0.95. The mother-tincture generally reveals two fluorescent blue colored stains with Rf near 0.55 and 0.85, another brown colored one with Rf near 0.95 corresponding to luteolin, and the last one, of red fluorescence, next to the mobile phase line. Nebulize the plate with aminoethanol diphenyl borate solution at 1% (p/v) in methanol. Let the plate air dry. Examine under ultraviolet light (365 nm). The stain corresponding to luteolin, of orange fluorescence, appears with Rf near 0.95 whilst those related to the testing mother-tincture appears with Rf ratings near respectively 0.55 and 0.85, of greenish yellow fluorescence.
- Develop one more chromatogram at the same previous conditions. Nebuliz the plate in chapel, with timol solution at 5% (p/v) in ethanol at 95% (v/v) and after with sulfuric acid at 10% (p/v). Heat the plate in stove at a temperature between 100 °C and 105 °C for 10 minutes. Examine under natural light. The chromatogram reveals pinky colored stain with Rf ranging from 0.00 to 0.10, two other also pinky colored ones with Rf near 0.20 and 0.25 and the last one, pink colored, with Rf near 0.55.

PURITY TESTS

- **Titration in ethanol.** Must range from 40% to 50% (v/v).
- **Dry residue.** Must be equal or higher than 1.25% (p/v).

PACKAGING AND STORAGE

- In neutral glass, amber, tightly close container, protected from light and heat.

DERIVED FORM

- **Starting point**. Mother-tincture.

This translation does not replace the portuguese version.

- **Inert ingredient.** From 1CH until 3Ch or 1DH until 6DH, use the same alcohol content of mother-tincture's. For the other applications, follow the general rule for preparing derived pharmaceutical forms.
- **Method.** *Hahnemannian Method* **(11.1)**, *Korsakovian Method* **(11.2)**, *Continuous flow method* **(11.3)**.
- **Dispensation.** From the mother-tincture, following dispensation general rule.
- **Packaging and storage.** In neutral glass, amber, tightly close container, protected from light and heat.

This translation does not replace the portuguese version.

THUYA OCCIDENTALIS

- *Thuya occidentalis* (L.) – CUPRESSACEAE

HOMEOPATHIC SYNONYMS
- Thuya, Arbor vitae.

APPLIED PART
- Young branches.

PLANT DESCRIPTION
- *Thuya occidentalis* L. is a tree which may achieve until 20 m in height, with its crown terminating in pyramidal crown with monopodial ramification to the stem. The erect stem is trunk type with reddish btown cortex revealing fairly branched sticks. The top branches reveal monoicous flowers. The branches are covered by small rigid leaves, itnerlocked among themselves. The leaves are oval shaped, persistent, with acuminate ends over a dorsal convex surface, revealing oval shaped gland at the angular end, containing resine oil of characteristic, intense odor, spicy, balsamic, camphoraceous odor. At the branches' ends, there are small yellow colored microsporophylled ovoid cones and male flowers. The fruit is megasporophylled oblong sub-conical strobile, brownish green.

DRUG DESCRIPTION
- The drug is constituted by young branches.

MOTHER-TINCTURE PREPARATION
- Proceed as described in *Preparation of Mother-tinctures from fresh plants* **(10.1.2)**. *Thuya occidentalis*'s mother-tincture is prepared by maceration with ethanol at 65% (v/v) from plant's young, fresh branches according to the general technique for preparing mother-tincture.

MOTHER-TINCTURE CHARACTERISTICS
- Greenish brown colored liquid, with characteristic, spicy, camphoraceous aromatic flavor, touch-resinous.

IDENTIFICATION
A. **A.** To 1 mL of mother-tincture, add three drops of Tollens reagent. It is observed reduction with creation of black precipitate whilst the supernatant solution assumes dark brown color. After, by heating it in boiling water bath for 1 minute, it is observed increase of precipitate amount.
B. To 1 mL of mother-tincture, add two drops of lead acetate solution at 1% (p/v). It is developed yellowish green color.
C. To 1 mL of mother-tincture, add five drops of sodium hydroxide solution at 10% (p/v). The solution turns turbid and assumes brown color.
D. To 1 mL of mother-tincture, add three drops of cupric sulfate solution at 5% (p/v). It is developed dark green color.
E. To 1 mL of mother-tincture, add one drop of ferric chloride solution at 10% (p/v). It is developed dark green color.

This translation does not replace the portuguese version.

F. To 1 mL of mother-tincture, add three drops of alkaline cupric tartrate SR. It is cooled developed yellowish green colored gelatinous precipitate.

G. To 1 mL of mother-tincture, add three drops of silver nitrate solution at 1% (p/v). It is developed yellowish green color with turbidity.

H. To 1 mL of mother-tincture, add two drops of potassium hydroxide solution at 10% (p/v). It is developed brown color. After, by heating in boiling water bath for 1 minute, the solution assumes gelatinous aspect.

I. To 1 mL of mother-tincture, add two drops of sodium hydroxide solution at 10% (p/v). It is developed greenish brown color with turbidity. After, by heating in boiling water bath for 1 minute, the color turns reddish brown.

J. To 1 mL of mother-tincture, add a few fragments of metalic magnesium and 1 mL of concentrated hydrochloric acid. It is developed dark red color.

K. To 1 mL of mother-tincture, add some resorcinol crystals. Allow it to boil in boiling water bath. It is developed dark red color.

L. Proceed as described in *Thin layer chromatography* **(5.2.17.1) FB 5**, using silica-gel G as support and mixture of ethyl acetate, anhydrous formic acid and water (80:10:10) as a mobile phase. Add 30 μL of mother-tincture to the plate. Develop the chromatogram for a course of 10 cm. Remove the plate, let it air dry. Examine under ultraviolet light (365 nm). It is observed tow stains of brown fluorescence with Rf near 0.60 and 0.70, and three other, superposed, respectively with Rf ranging from 0.90 and the front achieve by the mobile phase. It may occur another stain of blue fluorescence with Rf near 0.40. After, nebulize the plate with aminoethanol diphenyl borate SR. Examine under ultraviolet light (365 nm). It is observed two stains of orange fluorescence with Rf near 0.60 and 0.70, another one of yellow fluorescence with Rf near 0.80 and a forth one of yellow fluorescence and Rf near 0.95. As to previous revelation, it may be detected one last stain of light orange fluorescence and Rf near 0.45.

- Develop one more chromatogram using silica-gel G as support and mixture of chloroform and toluene (30:10) as a mobile phase. Add 20 μL of mother-tincture to the plate. Develop the chromatogram for a course of 10 cm. Remove the plate, let it air dry. Nebulize the plate with phosphomolybdic acid solution at 10% (p/v) in ethanol. Heat the plate in stove at a temperature of between 100 °C and 105 °C for 5 minutes. Examine under natural light. The chromatogram reveal six to seven stains dark blue colored with Rf ranging between the application point and the stain with Rf near 0.40, four other stains blueish colored with Rf ranging from 0.60 to 0.85, and the last one, dark blue colored, next to the front achieved by the mobile phase.
- Develop one more chromatogram using silica-gel G as support and mixture of chloroform and methanol (9:1) as a mobile phase. Add 30 μL of mother-tincture to the plate. Develop the chromatogram. Remove the plate, let it air dry. Examine under ultraviolet light (365 nm). The chromatogram reveals six stains of blue fluorescence with Rf near 0.05, 0.12, 0.37, 0.45, 0.72 and 0.85.

PURITY TESTS

- **Titration in ethanol.** Must range from 60% to 70% (v/v).
- **Dry residue.** Must be equal or higher than 1.3% (p/v).

PACKAGING AND STORAGE

- In neutral glass, amber, tightly close container, protected from light and heat.

This translation does not replace the portuguese version.

DERIVED FORM

- **Starting point.** Mother-tincture.
- **Inert ingredient.** At the first three hundreth applications and the first six decimal, use alcoholic content equals to mother-tincture's content.
- **Method.** *Hahnemannian Method* **(11.1)**, *Korsakovian Method* **(11.2)**, *Continuous flow method* **(11.3)**.
- **Dispensation.** From 1CH and 1DH, it will be applied ethanol with the same ethanol content as mother-tincture's, at first three applications for hundredth scale and first six application for decimal scale. From then, apply water-alcohol solution 30% (p/p).
- **Packaging and storage.** In neutral glass, amber, tightly close container, protected from light and heat.

This translation does not replace the portuguese version.

This translation does not replace the portuguese version.

16. REAGENTS

In this chapter, it is described the reagents e solutions related in Brazilian Homeopathic Pharmacopoeia, but they are not contemplated in *Reagents* **(14) FB 5**.

16.1 REAGENTS AND REAGENT SOLUTIONS

Aqua regia
- *Specification* – Mixture of fumegant nitric acid and hydrochloric acid (1:3). *Safety* – Corrosive.

Aniline
- *CAS* – [*62-53-3*]
- *Formula and molecular mass* – C_6H_7N – 93.13
- *Description* – Colorless or slightly yellowish colored liquid.
- *Physical characteristics* – Density (20 °C): about 1.02. Boiling range: 183 °C to 186 °C. *Solubility* – Soluble in water and miscible in ethanol.
- *Storage* – Protect from light.

Brucine
- *CAS* – [*357-57-3*]
- *Formula and molecular mass* – $C_{23}H_{26}N_2O_4.2H_2O$ – 430.50
- *Description* – Colorless crystals.
- *Physical characteristic* – Boiling temperature: about 178 °C.
- *Solubility* – Slightly soluble in water and easily soluble in ethanol.

Antimony chloride
- *CAS* – [*10025-91-9*]
- *Formula and molecular mass* – $SbCl_3$ – 228.12
- *Description* – Transparent crystalline mass or colorless crystals. Hygroscopic.
- *Solubility* – Easily soluble in ethanol. The antimony chloride is hydrolyzed by water. *Storage* – In closed containers, protected from humidity.

Diphenylamine hydrochloride
- *CAS* – [*537-67-7*]
- *Formula and molecular mass* – $C_{12}H_{11}N.HCl$ – 205.68
- *Description* – Crystals. They turn red upon contact with the air.
- *Solubility* – Easily soluble in water and ethanol.

Strontium chloride
- *CAS* – [*10025-70-4*]
- *Formula and molecular mass* – $SrCl_2.6H_2O$ – 266.60
- *Description* – White or nearly white colored crystals.
- *Solubility* – Fairly soluble in water.

This translation does not replace the portuguese version.

Ammonium chromate
- *CAS* – [*7788-98-9*]
- *Formula and molecular mass* – $CrH_8N_2O_4$ – 152.10
- *Description* – Yellow crystals.

Dichlorofluorescein
- *CAS* – [*76-54-0*]
- *Formula and molecular mass* – $C_{20}H_{10}Cl_2O_5$ – 401.20
- *Description* – Yellowish brown to yellowish orange colored powder.
- *Solubility* – Slightly soluble in water, easily soluble in ethanol and diluted hydroxy-alkaline solutions, forming solutions of yellowish green fluorescence.

Dichlorofluorescein SI
- *Preparation* – Dissolve 0,1 g of dichlorofluorescein in 60 mL of ethanol at 96% (v/v); add 2.5 mL of sodium hydroxide 0.1 *M*. Mix and complete the volume to 100 mL with purified water.

2.5-Dietoxitetrahydrofuran
- *CAS* – [*3320-90-9*]
- *Formula and molecular mass* – $C_8H_{16}O_3$ – 160.21
- *Specification* – Mixture of *cis* and *trans*.
- *Description* – Limpid, colorless to slightly yellowish colored liquid.
- *Physical characteristics* – Density (20 °C): about 0.98. Refractive index (20 °C): about 1.418.
- *Solubility* – Pratically insoluble in water, soluble in ethanol and other organic solvents.

Scopoletin
- *CAS* – [*92-61-5*]
- *Formula and molecular mass* – $C_{10}H_8O_4$ – 192.20
- *Description* – Light brown colored thin crystals.
- *Physical characteristic* – Fusion range: 202 °C to 208 °C.

Strychnine
- *CAS* – [*57-24-9*]
- *Formula and molecular mass* – $C_{21}H_{22}N_2O_2$ – 334.41
- *Physical characteristic* – Fusion range: 284 °C to 286 °C.
- *Safety* – Poison!

Phenylhydra zine
- *CAS* – [*100-23-0*]
- *Formula and molecular mass* – $C_6H_8N_2$ – 108.14
- *Description* – Monoclinic prism or oil. It turns yellowish to black whenever exposed to air or light.
- *Physical characteristics* – Density (20° C): 1.0978. Fusion temperature: 19.5° C. Boiling temperature: 243.5° C (with decomposition). Refraction index (20.3 °C): 1.6081.
- *Miscibility* – Miscible in ethanol, ethyl ether, chloroform and benzene. Slightly soluble in water and petroleum ether
- *Storage* – Protect from exposure to light.

This translation does not replace the portuguese version.

- *Conservation* – In tightly closed containers.

Isoquercetin
- *CAS* – [*482-35-9*]
- *Formula and molecular mass* – C21H20O12 – 464.38

Luteolin
- *CAS* – [*491-70-3*]
- *Formula and molecular mass* – C15H10O6 – 286.24

Magnesium mixture
- *Preparation* – Add 5.5 g of crystallized magnesium chloride to the solution formed by the dissolution of 7 g of ammonium chloride in 6 mL of purified water. Add to such solution 25 mL of ammonium hydroxide at 10% (v/v) and complete the volume to 100 mL. Allow it to rest for some days and apply the mixture.

Tollens reagents
- *Preparation* – To 10 mL of silver nitrate aqueous solution at 5% (p/v), add sufficient amount of ammonium hydroxide until the creation of brown colored precipitate and subsequent dissolution of it. After, add 5 mL of sodium hydroxide solution at 10% (p/v). In case the precipitate reappears, add drop by drop a new amount of ammonium hydroxide until it disappears.
- *Storage* – In dark container, with ground cover and preferably under refrigeration.

Hypophosphorous reagent
- *Preparation* – Dissolve it, blandly heating the preparation, 10 g of sodium hypophosphite in 20 mL of water and dilute for 100 mL with hydrochloric acid. Allow it to separate and decant or filter in glass wool.

Vanillin phosphoric reagent
- *Preparation* – Dissolver 1 g of vanillin in 100 mL of phosphoric acid at 50 % (p/v).

Solid blue B salt (CI 37235)
- *CAS* – [*84633-94-3*]
- *Formula and molecular mass* – C14H12Cl4N4O2Zn – 475.47
- *Description* – Dark green colored powder.
- *Solubility* – Soluble in water.
- *Storage* – In closed container.
- *Conservation* – Keep the temperature from 2 °C to 8 °C.

Epinephrine acid solution
- *Preparation* – Solubilize 1 mg of epinephrine in sufficient amount of hydrochloric acid *M* and complete it with purified water to 1 mL.

Aluminum chloride solution
- *Preparation* – In sufficient amount of methanol, add gradually, carefully 5 g of anhydrous aluminum chloride. Complete the volume to 100 mL with the same solvent.

This translation does not replace the portuguese version.

Aniline phthalate solution
- *Preparation* – Dissolve 0.93 g of aniline and 1.66 g of phthalic acid in 100 mL of saturated 1-butanol with purified water.
- *Conservation* – Keep it under refrigeration.

Calcium sulfate SR1
- *Preparation* – Add sufficient amount of anhydrous calcium sulfate to 10 mL of purified water until saturation. Allow it to rest until the supernatant turns limpid. Use the supernatant.

Lead pattern solution (2 ppm Pb)
- *Preparation* – Dilute exactly measured volume of *Lead pattern solution (10 ppm Pb)* prepared as described in *Limit test for heavy metals* **(5.3.2.3) FB 5** with 5 volumes of water.

Iron pattern solution (1 ppm Fe)
- *Preparation* – Dilute 1 mL of *Iron pattern solution (100 ppm Fe)* prepared as described in *Limit test for iron* **(5.3.2.4) FB 5**, with distilled water and complete the volume to 100 mL.

16.2 VOLUMETRIC SOLUTION

Potassium thiocyanate 0.1 *M* SV
- *Preparation* – Dissolve about 9.7 g of potassium thiocyanate in water to 1000 mL.
- *Standardization* – Measure with volumetric pipette a rate of 10 mL of silver nitrate 0.1 *M* SV and transfer to an erlenmeyer. Add 1 mL of ammoniacal ferric sulfate at 40% (p/v), as indicator and 5 mL of nitric acid 6 *M*. Titrate it with the thiocyanate solution until the first reddish color. Continue the titration with strong shaking until the appearance of a reddish brown color, which persists even under strong shaking. Repeat it two more times. Calculate the molarity and the correction factor of potassium thiocyanate.
- *Conservation* – Tightly closed containers.

16.3 BUFFER

Acid phthalate buffer pH 4.0
- *Preparation* – Dissolve 2.042 g of potassium biphthalate in 50 mL of water, add 7.5 mL of hydrogen hydroxide 0.2 *M* and dilute it to 200 mL in water. Set pH to 4.0, if necessary.

This translation does not replace the portuguese version.

ATTACHMENT A – MESH AND TAMISES' OPENING EQUIVALENCE

Table A – Table for mesh and tamises' opening equivalence

	ASTM ABNT	TYLER MESH	OPENING IN MILLIMETER	OPENING IN INCHES
THICK SERIES	4 Inches	-	101.4	4.00
	3 ½ Inches	-	88.9	3.50
	3 Inches	-	76.2	3.00
	2 1/2 Inches	-	63.5	2.50
	2 Inches	-	50.8	2.00
	1 ¾ Inches	-	44.4	1.75
	1 ½ Inches	-	38.1	1.50
	1 ¼ Inches	-	31.7	1.25
	1 Inches	-	25.4	1.00
	¾ Inches	-	19.1	0.75
	5/8 Inches	-	15.9	0.625
	½ Inches	-	12.7	0.500
	3/8 Inches	-	9.52	0.375
	3/16 Inches	-	7.93	0.312
	¼ Inches	-	6.35	0.250
THIN RANGE	3.5	3.5	5.66	0.223
	4	4	4.76	0.187
	5	5	4.00	0.157
	6	6	3.36	0.132
	7	7	2.83	0.111
	8	8	2.38	0.0937
	10	10	2.00	0.0787
	12	12	1.65	0.0661
	14	14	1.41	0.0555
	16	16	1.19	0.0469
	18	18	1.00	0.0394
	20	20	0.84	0.0331
	25	25	0.71	0.0280
	30	30	0.59	0.0232
	35	35	0.50	0.0197
	40	40	0.42	0.0165
	45	45	0.35	0.0135
	50	50	0.297	0.0117
	60	60	0.250	0.0092
	70	70	0.210	0.0083
	80	80	0.177	0.0070
	100	100	0.149	0.0059
	120	120	0.125	0.0049
	140	140	0.105	0.0041
	170	170	0.088	0.0035
	200	200	0.074	0.0029
	230	230	0.062	0.0024
	270	270	0.053	0.0021
	325	325	0.044	0.0017
	400	400	0.037	0.0015
	500	500	0.025	0.0010

This translation does not replace the portuguese version.

This translation does not replace the portuguese version.

ATTACHMENT B - CONVERTION FROM NORMALITY TO MOLARITY

Conversion from normality to molarity, related to constant reagent solution in Brazilian Homeopathic Pharmacopoeia, 3rd edition.

Hydrochloric acid *N*	*M* or 1 mol L^{-1}
Nitric acid *N*	*M* or 1 mol L^{-1}
Perchloric acid *N*	*M* or 1 mol L^{-1}
Sulfuric acid *N*	0,5 *M* or 0,5 mol L^{-1}
Barium chloride *N*	0,5 *M* or 0,5 mol L^{-1}
Ferric chloride *N*	0,33 ... *M* or 0,33 ... mol L^{-1}
Sodium hydroxide *N*	*M* or 1 mol L^{-1}
Potassium iodate *N*	*M* or 1 mol L^{-1}
Silver nitrate *N*	*M* or 1 mol L^{-1}
Potassium permanganate *N*	0,2 *M* or 0,2 mol L^{-1}
Cerium sulfate *N*	*M* or 1 mol L^{-1}
Potassium thiocyanate *N*	*M* or 1 mol L^{-1}
Sodium thiosulfate *N*	*M* or 1 mol L^{-1}

This translation does not replace the portuguese version.

This translation does not replace the portuguese version.

ATTACHMENT C - ALCOHOLOMETRY

Table C – Alcoholometric Table (20 °C)

% v/v	% m/m	ϱ20 (Kg/m³)	d (g/cm³)
0,0	0,0	998,20	0,999997
0,1	0,08	998,05	0,999846
0,2	0,16	997,90	0,999696
0,3	0,24	997,75	0,999546
0,4	0,32	997,59	0,999386
0,5	0,40	997,44	0,999235
0,6	0,47	997,29	0,999085
0,7	0,55	997,14	0,998935
0,8	0,63	996,99	0,998785
0,9	0,71	996,85	0,998644
1,0	0,79	996,70	0,998494
1,1	0,87	996,55	0,998344
1,2	0,95	996,40	0,998194
1,3	1,03	996,25	0,998043
1,4	1,11	996,11	0,997903
1,5	1,19	995,96	0,997753
1,6	1,27	995,81	0,997602
1,7	1,35	995,67	0,997462
1,8	1,43	995,52	0,997312
1,9	1,51	995,38	0,997172
2,0	1,59	995,23	0,997021
2,1	1,67	995,09	0,996881
2,2	1,75	994,94	0,996731
2,3	1,82	994,80	0,996591
2,4	1,90	994,66	0,996450
2,5	1,98	994,51	0,996300
2,6	2,06	994,37	0,996160
2,7	2,14	994,23	0,996020
2,8	2,22	994,09	0,995879
2,9	2,30	993,95	0,995739
3,0	2,38	993,81	0,995599
3,1	2,46	993,66	0,995449
3,2	2,54	993,52	0,995308
3,3	2,62	993,38	0,995168
3,4	2,70	993,24	0,995028
3,5	2,78	993,11	0,994898
3,6	2,86	992,97	0,994757
3,7	2,94	992,83	0,994617
3,8	3,02	992,69	0,994477
3,9	3,10	992,55	0,994337
4,0	3,18	992,41	0,994196
4,1	3,26	992,28	0,994066
4,2	3,34	992,14	0,993926
4,3	3,42	992,00	0,993786
4,4	3,50	991,87	0,993655
4,5	3,58	991,73	0,993515
4,6	3,66	991,59	0,993375
4,7	3,74	991,46	0,993245
4,8	3,82	991,32	0,993104
4,9	3,90	991,19	0,992974
5,0	3,98	991,06	0,992844
5,1	4,06	990,92	0,992704
5,2	4,14	990,79	0,992573
5,3	4,22	990,65	0,992433
5,4	4,30	990,52	0,992303
5,5	4,38	990,39	0,992173

This translation does not replace the portuguese version.

This translation does not replace the portuguese version.

% v/v	% m/m	ϱ20 (Kg/m³)	d (g/cm³)
5,6	4,46	990,26	0,992042
5,7	4,54	990,12	0,991902
5,8	4,62	989,99	0,991772
5,9	4,70	989,86	0,991642
6,0	4,78	989,73	0,991512
6,1	4,87	989,60	0,991381
6,2	4,95	989,47	0,991251
6,3	5,03	989,34	0,991121
6,4	5,11	989,21	0,990991
6,5	5,19	989,08	0,990860
6,6	5,27	988,95	0,990730
6,7	5,35	988,82	0,990600
6,8	5,43	988,69	0,990470
6,9	5,51	988,56	0,990339
7,0	5,59	988,43	0,990209
7,1	5,67	988,30	0,990079
7,2	5,75	988,18	0,989959
7,3	5,83	988,05	0,989828
7,4	5,91	987,92	0,989698
7,5	5,99	987,79	0,989568
7,6	6,07	987,67	0,989448
7,7	6,15	987,54	0,989318
7,8	6,23	987,42	0,989197
7,9	6,32	987,29	0,989067
8,0	6,40	987,16	0,988937
8,1	6,48	987,04	0,988817
8,2	6,56	986,91	0,988686
8,3	6,64	986,79	0,988566
8,4	6,72	986,66	0,988436
8,5	6,80	986,54	0,988316
8,6	6,88	986,42	0,988196
8,7	6,96	986,29	0,988065
8,8	7,04	986,17	0,987945
8,9	7,12	986,05	0,987825
9,0	7,20	985,92	0,987695
9,1	7,29	985,80	0,987574
9,2	7,37	985,68	0,987454
9,3	7,45	985,56	0,987334
9,4	7,53	985,44	0,987214
9,5	7,61	985,31	0,987084
9,6	7,69	985,19	0,986963
9,7	7,77	985,07	0,986843
9,8	7,85	984,95	0,986723
9,9	7,93	984,83	0,986603
10,0	8,01	984,71	0,986482
10,1	8,10	984,59	0,986362
10,2	8,18	984,47	0,986242
10,3	8,26	984,35	0,986122
10,4	8,34	984,23	0,986002
10,5	8,42	984,11	0,985881
10,6	8,50	983,99	0,985761
10,7	8,58	983,88	0,985651
10,8	8,66	983,76	0,985531
10,9	8,75	983,64	0,985411
11,0	8,83	983,52	0,985290
11,1	8,91	983,40	0,985170
11,2	8,99	983,29	0,985060
11,3	9,07	983,17	0,984940
11,4	9,15	983,05	0,984819
11,5	9,23	982,94	0,984709

This translation does not replace the portuguese version.

% v/v	% m/m	ϱ20 (Kg/m³)	d (g/cm³)
11,6	9,32	982,82	0,984589
11,7	9,40	982,70	0,984469
11,8	9,48	982,59	0,984359
11,9	9,56	982,47	0,984238
12,0	9,64	982,35	0,984118
12,1	9,72	982,24	0,984008
12,2	9,80	982,12	0,983888
12,3	9,89	982,01	0,983778
12,4	9,97	981,89	0,983657
12,5	10,05	981,78	0,983547
12,6	10,13	981,67	0,983437
12,7	10,21	981,55	0,983317
12,8	10,29	981,44	0,983207
12,9	10,37	981,32	0,983086
13,0	10,46	981,21	0,982976
13,1	10,54	981,10	0,982866
13,2	10,62	980,98	0,982746
13,3	10,70	980,87	0,982636
13,4	10,78	980,76	0,982525
13,5	10,87	980,64	0,982405
13,6	10,95	980,53	0,982295
13,7	11,03	980,42	0,982185
13,8	11,11	980,31	0,982075
13,9	11,19	980,19	0,981954
14,0	11,27	980,08	0,981844
14,1	11,36	979,97	0,981734
14,2	11,44	979,86	0,981624
14,3	11,52	979,75	0,981514
14,4	11,60	979,64	0,981403
14,5	11,68	979,52	0,981283
14,6	11,77	979,41	0,981173
14,7	11,85	979,30	0,981063
14,8	11,93	979,19	0,980953
14,9	12,01	979,08	0,980842
15,0	12,09	978,97	0,980732
15,1	12,17	978,86	0,980622
15,2	12,26	978,75	0,980512
15,3	12,34	978,64	0,980402
15,4	12,42	978,53	0,980291
15,5	12,50	978,42	0,980181
15,6	12,59	978,31	0,980071
15,7	12,67	978,20	0,979961
15,8	12,75	978,09	0,979851
15,9	12,83	977,98	0,979740
16,0	12,91	977,87	0,979630
16,1	13,00	977,76	0,979520
16,2	13,08	977,65	0,979410
16,3	13,16	977,55	0,979310
16,4	13,24	977,44	0,979199
16,5	13,32	977,33	0,979089
16,6	13,41	977,22	0,978979
16,7	13,49	977,11	0,978869
16,8	13,57	977,00	0,978759
16,9	13,65	976,89	0,978648
17,0	13,74	976,79	0,978548
17,1	13,82	976,68	0,978438
17,2	13,90	976,57	0,978328
17,3	13,98	976,46	0,978218
17,4	14,07	976,35	0,978107
17,5	14,15	976,25	0,978007

This translation does not replace the portuguese version.

% v/v	% m/m	ϱ20 (Kg/m³)	d (g/cm³)
17,6	14,23	976,14	0,977897
17,7	14,31	976,03	0,977787
17,8	14,40	975,92	0,977677
17,9	14,48	975,81	0,977566
18,0	14,56	975,71	0,977466
18,1	14,64	975,60	0,977356
18,2	14,73	975,49	0,977246
18,3	14,81	975,38	0,977136
18,4	14,89	975,28	0,977036
18,5	14,97	975,17	0,976925
18,6	15,06	975,06	0,976815
18,7	15,14	974,95	0,976705
18,8	15,22	974,85	0,976605
18,9	15,30	974,74	0,976495
19,0	15,39	974,63	0,976384
19,1	15,47	974,52	0,976274
19,2	15,55	974,42	0,976174
19,3	15,63	974,31	0,976064
19,4	15,72	974,20	0,975954
19,5	15,80	974,09	0,975843
19,6	15,88	973,99	0,975743
19,7	15,97	973,88	0,975633
19,8	16,05	973,77	0,975523
19,9	16,13	973,66	0,975413
20,0	16,21	973,56	0,975312
20,1	16,30	973,45	0,975202
20,2	16,38	973,34	0,975092
20,3	16,46	973,24	0,974992
20,4	16,55	973,13	0,974882
20,5	16,63	973,02	0,974771
20,6	16,71	972,91	0,974661
20,7	16,79	972,80	0,974551
20,8	16,88	972,70	0,974451
20,9	16,96	972,59	0,974341
21,0	17,04	972,48	0,974230
21,1	17,13	972,37	0,974120
21,2	17,21	972,26	0,974010
21,3	17,29	972,16	0,973910
21,4	17,38	972,05	0,973800
21,5	17,46	971,94	0,973689
21,6	17,54	971,83	0,973579
21,7	17,63	971,73	0,973479
21,8	17,71	971,62	0,973369
21,9	17,79	971,51	0,973259
22,0	17,87	971,40	0,973149
22,1	17,96	971,29	0,973038
22,2	18,04	971,18	0,972928
22,3	18,12	971,08	0,972828
22,4	18,21	970,97	0,972718
22,5	18,29	970,86	0,972608
22,6	18,37	970,75	0,972497
22,7	18,46	970,64	0,972387
22,8	18,54	970,53	0,972277
22,9	18,62	970,42	0,972167
23,0	18,71	970,31	0,972057
23,1	18,79	970,20	0,971946
23,2	18,87	970,09	0,971836
23,3	18,96	969,98	0,971726
23,4	19,04	969,87	0,971616
23,5	19,13	969,76	0,971506

This translation does not replace the portuguese version.

% v/v	% m/m	ϱ20 (Kg/m³)	d (g/cm³)
23,6	19,21	969,65	0,971395
23,7	19,29	969,54	0,971285
23,8	19,38	969,43	0,971175
23,9	19,46	969,32	0,971065
24,0	19,54	969,21	0,970955
24,1	19,63	969,10	0,970844
24,2	19,71	968,99	0,970734
24,3	19,79	968,88	0,970624
24,4	19,88	968,77	0,970514
24,5	19,96	968,66	0,970404
24,6	20,05	968,55	0,970293
24,7	20,13	968,43	0,970173
24,8	20,21	968,32	0,970063
24,9	20,30	968,21	0,969953
25,0	20,38	968,10	0,969843
25,1	20,47	967,99	0,969732
25,2	20,55	967,87	0,969612
25,3	20,63	967,76	0,969502
25,4	20,72	967,65	0,969392
25,5	20,80	967,53	0,969272
25,6	20,89	967,42	0,969161
25,7	20,97	967,31	0,969051
25,8	21,05	967,19	0,968931
25,9	21,14	967,08	0,968821
26,0	21,22	966,97	0,968711
26,1	21,31	966,85	0,968590
26,2	21,39	966,74	0,968480
26,3	21,47	966,62	0,968360
26,4	21,56	966,51	0,968250
26,5	21,64	966,39	0,968130
26,6	21,73	966,28	0,968019
26,7	21,81	966,16	0,967899
26,8	21,90	966,05	0,967789
26,9	21,98	965,93	0,967669
27,0	22,06	965,81	0,967548
27,1	22,15	965,70	0,967438
27,2	22,23	965,58	0,967318
27,3	22,32	965,46	0,967198
27,4	22,40	965,35	0,967088
27,5	22,49	965,23	0,966967
27,6	22,57	965,11	0,966847
27,7	22,65	964,99	0,966727
27,8	22,74	964,88	0,966617
27,9	22,82	964,76	0,966497
28,0	22,91	964,64	0,966376
28,1	22,99	964,52	0,966256
28,2	23,08	964,40	0,966136
28,3	23,16	964,28	0,966016
28,4	23,25	964,16	0,965895
28,5	23,33	964,04	0,965775
28,6	23,42	963,92	0,965655
28,7	23,50	963,80	0,965535
28,8	23,59	963,68	0,965415
28,9	23,67	963,56	0,965294
29,0	23,76	963,44	0,965174
29,1	23,84	963,32	0,965054
29,2	23,93	963,20	0,964934
29,3	24,01	963,07	0,964804
29,4	24,10	962,95	0,964683
29,5	24,18	962,83	0,964563

This translation does not replace the portuguese version.

% v/v	% m/m	ϱ20 (Kg/m³)	d (g/cm³)
29,6	24,27	962,71	0,964443
29,7	24,35	962,58	0,964313
29,8	24,44	962,46	0,964192
29,9	24,52	962,33	0,964062
30,0	24,61	962,21	0,963942
30,1	24,69	962,09	0,963822
30,2	24,78	961,96	0,963692
30,3	24,86	961,84	0,963571
30,4	24,95	961,71	0,963441
30,5	25,03	961,59	0,963321
30,6	25,12	961,46	0,963191
30,7	25,20	961,33	0,963060
30,8	25,29	961,21	0,962940
30,9	25,38	961,08	0,962810
31,0	25,46	960,95	0,962680
31,1	25,55	960,82	0,962549
31,2	25,63	960,70	0,962429
31,3	25,72	960,57	0,962299
31,4	25,80	960,44	0,962169
31,5	25,89	960,31	0,962039
31,6	25,97	960,18	0,961908
31,7	26,06	960,05	0,961778
31,8	26,15	959,92	0,961648
31,9	26,23	959,79	0,961518
32,0	26,32	959,66	0,961387
32,1	26,40	959,53	0,961257
32,2	26,49	959,40	0,961127
32,3	26,57	959,27	0,960997
32,4	26,66	959,14	0,960866
32,5	26,75	959,01	0,960736
32,6	26,83	958,87	0,960596
32,7	26,92	958,74	0,960466
32,8	27,00	958,61	0,960335
32,9	27,09	958,47	0,960195
33,0	27,18	958,34	0,960065
33,1	27,26	958,20	0,959925
33,2	27,35	958,07	0,959795
33,3	27,44	957,94	0,959664
33,4	27,52	957,80	0,959524
33,5	27,61	957,66	0,959384
33,6	27,69	957,53	0,959254
33,7	27,78	957,39	0,959113
33,8	27,87	957,26	0,958983
33,9	27,95	957,12	0,958843
34,0	28,04	956,98	0,958703
34,1	28,13	956,84	0,958562
34,2	28,21	956,70	0,958422
34,3	28,30	956,57	0,958292
34,4	28,39	956,43	0,958152
34,5	28,47	956,29	0,958011
34,6	28,56	956,15	0,957871
34,7	28,65	956,01	0,957731
34,8	28,73	955,87	0,957591
34,9	28,82	955,73	0,957450
35,0	28,91	955,59	0,957310
35,1	28,99	955,45	0,957170
35,2	29,08	955,30	0,957020
35,3	29,17	955,16	0,956879
35,4	29,26	955,02	0,956739
35,5	29,34	954,88	0,956599

This translation does not replace the portuguese version.

% v/v	% m/m	ϱ20 (Kg/m³)	d (g/cm³)
35,6	29,43	954,73	0,956449
35,7	29,52	954,59	0,956308
35,8	29,60	954,44	0,956158
35,9	29,69	954,30	0,956018
36,0	29,78	954,15	0,955867
36,1	29,87	954,01	0,955727
36,2	29,95	953,86	0,955577
36,3	30,04	953,72	0,955437
36,4	30,13	953,57	0,955286
36,5	30,22	953,42	0,955136
36,6	30,30	953,28	0,954996
36,7	30,39	953,13	0,954846
36,8	30,48	952,98	0,954695
36,9	30,56	952,83	0,954545
37,0	30,65	952,69	0,954405
37,1	30,74	952,54	0,954255
37,2	30,83	952,39	0,954104
37,3	30,92	952,24	0,953954
37,4	31,00	952,09	0,953804
37,5	31,09	951,94	0,953653
37,6	31,18	951,79	0,953503
37,7	31,27	951,63	0,953343
37,8	31,35	951,48	0,953193
37,9	31,44	951,33	0,953042
38,0	31,53	951,18	0,952892
38,1	31,62	951,02	0,952732
38,2	31,71	950,87	0,952582
38,3	31,79	950,72	0,952431
38,4	31,88	950,56	0,952271
38,5	31,97	950,41	0,952121
38,6	32,06	950,25	0,951960
38,7	32,15	950,10	0,951810
38,8	32,24	949,94	0,951650
38,9	32,32	949,79	0,951500
39,0	32,41	949,63	0,951339
39,1	32,50	949,47	0,951179
39,2	32,59	949,32	0,951029
39,3	32,68	949,16	0,950868
39,4	32,77	949,00	0,950708
39,5	32,86	948,84	0,950548
39,6	32,94	948,68	0,950388
39,7	33,03	948,52	0,950227
39,8	33,12	948,37	0,950077
39,9	33,21	948,21	0,949917
40,0	33,30	948,05	0,949756
40,1	33,39	947,88	0,949586
40,2	33,48	947,72	0,949426
40,3	33,57	947,56	0,949266
40,4	33,66	947,40	0,949105
40,5	33,74	947,24	0,948945
40,6	33,83	947,08	0,948785
40,7	33,92	946,91	0,948614
40,8	34,01	946,75	0,948454
40,9	34,10	946,58	0,948284
41,0	34,19	946,42	0,948124
41,1	34,28	946,26	0,947963
41,2	34,37	946,09	0,947793
41,3	34,46	945,93	0,947633
41,4	34,55	945,76	0,947462
41,5	34,64	945,59	0,947292

This translation does not replace the portuguese version.

% v/v	% m/m	ϱ20 (Kg/m³)	d (g/cm³)
41,6	34,73	945,43	0,947132
41,7	34,82	945,26	0,946961
41,8	34,91	945,09	0,946791
41,9	35,00	944,93	0,946631
42,0	35,09	944,76	0,946461
42,1	35,18	944,59	0,946290
42,2	35,27	944,42	0,946120
42,3	35,36	944,25	0,945950
42,4	35,45	944,08	0,945779
42,5	35,54	943,91	0,945609
42,6	35,63	943,74	0,945439
42,7	35,72	943,57	0,945268
42,8	35,81	943,40	0,945098
42,9	35,90	943,23	0,944928
43,0	35,99	943,06	0,944758
43,1	36,08	942,88	0,944577
43,2	36,17	942,71	0,944407
43,3	36,26	942,54	0,944237
43,4	36,35	942,37	0,944066
43,5	36,44	942,19	0,943886
43,6	36,53	942,02	0,943716
43,7	36,62	941,84	0,943535
43,8	36,71	941,67	0,943365
43,9	36,80	941,49	0,943185
44,0	36,89	941,32	0,943014
44,1	36,98	941,14	0,942834
44,2	37,07	940,97	0,942664
44,3	37,16	940,79	0,942483
44,4	37,25	940,61	0,942303
44,5	37,35	940,43	0,942123
44,6	37,44	940,26	0,941952
44,7	37,53	940,08	0,941772
44,8	37,62	939,90	0,941592
44,9	37,71	939,72	0,941411
45,0	37,80	939,54	0,941231
45,1	37,89	939,36	0,941051
45,2	37,98	939,18	0,940871
45,3	38,08	939,00	0,940690
45,4	38,17	938,82	0,940510
45,5	38,26	938,64	0,940330
45,6	38,35	938,46	0,940149
45,7	38,44	938,28	0,939969
45,8	38,53	938,10	0,939789
45,9	38,62	937,91	0,939598
46,0	38,72	937,73	0,939418
46,1	38,81	937,55	0,939238
46,2	38,90	937,36	0,939047
46,3	38,99	937,18	0,938867
46,4	39,08	937,00	0,938687
46,5	39,18	936,81	0,938496
46,6	39,27	936,63	0,938316
46,7	39,36	936,44	0,938126
46,8	39,45	936,26	0,937945
46,9	39,54	936,07	0,937755
47,0	39,64	935,88	0,937565
47,1	39,73	935,70	0,937384
47,2	39,82	935,51	0,937194
47,3	39,91	935,32	0,937004
47,4	40,00	935,14	0,936823
47,5	40,10	934,95	0,936633

This translation does not replace the portuguese version.

% v/v	% m/m	ϱ20 (Kg/m³)	d (g/cm³)
47,6	40,19	934,76	0,936443
47,7	40,28	934,57	0,936252
47,8	40,37	934,38	0,936062
47,9	40,47	934,19	0,935872
48,0	40,56	934,00	0,935681
48,1	40,65	933,81	0,935491
48,2	40,75	933,62	0,935301
48,3	40,84	933,43	0,935110
48,4	40,93	933,24	0,934920
48,5	41,02	933,05	0,934729
48,6	41,12	932,86	0,934539
48,7	41,21	932,67	0,934349
48,8	41,30	932,47	0,934148
48,9	41,40	932,28	0,933958
49,0	41,49	932,09	0,933768
49,1	41,58	931,90	0,933577
49,2	41,68	931,70	0,933377
49,3	41,77	931,51	0,933187
49,4	41,86	931,32	0,932996
49,5	41,96	931,13	0,932806
49,6	42,05	930,92	0,932596
49,7	42,14	930,73	0,932405
49,8	42,24	930,53	0,932205
49,9	42,33	930,34	0,932015
50,0	42,43	930,14	0,931814
50,1	42,52	929,95	0,931624
50,2	42,61	929,75	0,931424
50,3	42,71	929,55	0,931223
50,4	42,80	929,35	0,931023
50,5	42,90	929,16	0,930832
50,6	42,99	928,96	0,930632
50,7	43,08	928,76	0,930432
50,8	43,18	928,56	0,930231
50,9	43,27	928,36	0,930031
51,0	43,37	928,16	0,929831
51,1	43,46	927,96	0,929630
51,2	43,56	927,77	0,929440
51,3	43,65	927,57	0,929240
51,4	43,74	927,36	0,929029
51,5	43,84	927,16	0,928829
51,6	43,93	926,96	0,928629
51,7	44,03	926,76	0,928428
51,8	44,12	926,56	0,928228
51,9	44,22	926,36	0,928027
52,0	44,31	926,16	0,927827
52,1	44,41	925,95	0,927617
52,2	44,50	925,75	0,927416
52,3	44,60	925,55	0,927216
52,4	44,69	925,35	0,927016
52,5	44,79	925,14	0,926805
52,6	44,88	924,94	0,926605
52,7	44,98	924,73	0,926395
52,8	45,07	924,53	0,926194
52,9	45,17	924,32	0,925984
53,0	45,26	924,12	0,925783
53,1	45,36	923,91	0,925573
53,2	45,46	923,71	0,925373
53,3	45,55	923,50	0,925162
53,4	45,65	923,30	0,924962
53,5	45,74	923,09	0,924752

This translation does not replace the portuguese version.

% v/v	% m/m	ϱ20 (Kg/m³)	d (g/cm³)
53,6	45,84	922,88	0,924541
53,7	45,93	922,68	0,924341
53,8	46,03	922,47	0,924130
53,9	46,13	922,26	0,923920
54,0	46,22	922,06	0,923720
54,1	46,32	921,85	0,923509
54,2	46,41	921,64	0,923299
54,3	46,51	921,43	0,923089
54,4	46,61	921,22	0,922878
54,5	46,70	921,01	0,922668
54,6	46,80	920,80	0,922457
54,7	46,90	920,59	0,922247
54,8	46,99	920,38	0,922037
54,9	47,09	920,17	0,921826
55,0	47,18	919,96	0,921616
55,1	47,28	919,75	0,921406
55,2	47,38	919,54	0,921195
55,3	47,47	919,33	0,920985
55,4	47,57	919,12	0,920774
55,5	47,67	918,91	0,920564
55,6	47,77	918,69	0,920344
55,7	47,86	918,48	0,920133
55,8	47,96	918,27	0,919923
55,9	48,06	918,06	0,919713
56,0	48,15	917,84	0,919492
56,1	48,25	917,63	0,919282
56,2	48,35	917,42	0,919071
56,3	48,45	917,22	0,918871
56,4	48,54	916,99	0,918641
56,5	48,64	916,77	0,918420
56,6	48,74	916,56	0,918210
56,7	48,84	916,35	0,917999
56,8	48,94	916,13	0,917779
56,9	49,03	915,91	0,917559
57,0	49,13	915,70	0,917348
57,1	49,23	915,48	0,917128
57,2	49,32	915,27	0,916917
57,3	49,42	915,05	0,916697
57,4	49,52	914,83	0,916477
57,5	49,62	914,62	0,916266
57,6	49,72	914,40	0,916046
57,7	49,81	914,18	0,915826
57,8	49,91	913,97	0,915615
57,9	50,01	913,75	0,915395
58,0	50,11	913,53	0,915174
58,1	50,21	913,31	0,914954
58,2	50,31	913,09	0,914734
58,3	50,40	912,87	0,914513
58,4	50,50	912,65	0,914293
58,5	50,60	912,43	0,914072
58,6	50,70	912,22	0,913862
58,7	50,80	912,00	0,913642
58,8	50,90	911,78	0,913421
58,9	51,00	911,55	0,913191
59,0	51,10	911,33	0,912970
59,1	51,19	911,11	0,912750
59,2	51,29	910,89	0,912530
59,3	51,39	910,67	0,912309
59,4	51,49	910,45	0,912089
59,5	51,59	910,23	0,911868

This translation does not replace the portuguese version.

% v/v	% m/m	ϱ20 (Kg/m³)	d (g/cm³)
59,6	51,69	910,01	0,911648
59,7	51,79	909,78	0,911418
59,8	51,89	909,56	0,911197
59,9	51,99	909,34	0,910977
60,0	52,09	909,11	0,910746
60,1	52,19	908,89	0,910526
60,2	52,29	908,67	0,910306
60,3	52,39	908,44	0,910075
60,4	52,49	908,22	0,909855
60,5	52,59	908,00	0,909634
60,6	52,69	907,77	0,909404
60,7	52,79	907,55	0,909184
60,8	52,89	907,32	0,908953
60,9	52,99	907,10	0,908733
61,0	53,09	906,87	0,908502
61,1	53,19	906,64	0,908272
61,2	53,29	906,42	0,908052
61,3	53,39	906,19	0,907821
61,4	53,49	905,97	0,907601
61,5	53,59	905,74	0,907370
61,6	53,69	905,51	0,907140
61,7	53,79	905,29	0,906920
61,8	53,89	905,06	0,906689
61,9	53,99	904,83	0,906459
62,0	54,09	904,60	0,906228
62,1	54,19	904,37	0,905998
62,2	54,30	904,15	0,905777
62,3	54,40	903,92	0,905547
62,4	54,50	903,69	0,905317
62,5	54,60	903,46	0,905086
62,6	54,70	903,23	0,904856
62,7	54,80	903,00	0,904625
62,8	54,90	902,77	0,904395
62,9	55,00	902,54	0,904165
63,0	55,11	902,31	0,903934
63,1	55,21	902,08	0,903704
63,2	55,31	901,85	0,903473
63,3	55,41	901,62	0,903243
63,4	55,51	901,39	0,903013
63,5	55,61	901,15	0,902772
63,6	55,72	900,92	0,902542
63,7	55,82	900,69	0,902311
63,8	55,92	900,46	0,902081
63,9	56,02	900,23	0,901850
64,0	56,12	899,99	0,901610
64,1	56,23	899,76	0,901380
64,2	56,33	899,53	0,901149
64,3	56,43	899,29	0,900909
64,4	56,53	899,06	0,900678
64,5	56,64	898,83	0,900448
64,6	56,74	898,59	0,900207
64,7	56,84	898,36	0,899977
64,8	56,94	898,12	0,899737
64,9	57,05	897,89	0,899506
65,0	57,15	897,65	0,899266
65,1	57,25	897,42	0,899035
65,2	57,36	897,18	0,898795
65,3	57,46	896,94	0,898554
65,4	57,56	896,71	0,898324
65,5	57,67	896,47	0,898084

This translation does not replace the portuguese version.

% v/v	% m/m	ϱ20 (Kg/m³)	d (g/cm³)
65,6	57,77	896,23	0,897843
65,7	57,87	896,00	0,897613
65,8	57,98	895,76	0,897372
65,9	58,08	895,52	0,897132
66,0	58,18	895,28	0,896892
66,1	58,29	895,05	0,896661
66,2	58,39	894,81	0,896421
66,3	58,49	894,57	0,896180
66,4	58,60	894,33	0,895940
66,5	58,70	894,09	0,895699
66,6	58,81	893,85	0,895459
66,7	58,91	893,61	0,895218
66,8	59,01	893,37	0,894978
66,9	59,12	893,13	0,894738
67,0	59,22	892,89	0,894497
67,1	59,33	892,65	0,894257
67,2	59,43	892,41	0,894016
67,3	59,54	892,17	0,893776
67,4	59,64	891,93	0,893535
67,5	59,74	891,69	0,893295
67,6	59,85	891,45	0,893055
67,7	59,95	891,20	0,892804
67,8	60,06	890,96	0,892564
67,9	60,16	890,72	0,892323
68,0	60,27	890,48	0,892083
68,1	60,37	890,23	0,891832
68,2	60,48	889,99	0,891592
68,3	60,58	889,75	0,891352
68,4	60,69	889,50	0,891101
68,5	60,80	889,26	0,890861
68,6	60,90	889,01	0,890610
68,7	61,01	888,77	0,890370
68,8	61,11	888,52	0,890119
68,9	61,22	888,28	0,889879
69,0	61,32	888,03	0,889628
69,1	61,43	887,79	0,889388
69,2	61,54	887,54	0,889138
69,3	61,64	887,29	0,888887
69,4	61,75	887,05	0,888647
69,5	61,85	886,80	0,888396
69,6	61,96	886,55	0,888146
69,7	62,07	886,31	0,887905
69,8	62,17	886,06	0,887655
69,9	62,28	885,81	0,887404
70,0	62,39	885,56	0,887154
70,1	62,49	885,31	0,886904
70,2	62,60	885,06	0,886653
70,3	62,71	884,82	0,886413
70,4	62,81	884,57	0,886162
70,5	62,92	884,32	0,885912
70,6	63,03	884,07	0,885661
70,7	63,13	883,82	0,885411
70,8	63,24	883,57	0,885160
70,9	63,35	883,32	0,884910
71,0	63,46	883,06	0,884650
71,1	63,56	882,81	0,884399
71,2	63,67	882,56	0,884149
71,3	63,78	882,31	0,883898
71,4	63,89	882,06	0,883648
71,5	63,99	881,81	0,883397

This translation does not replace the portuguese version.

% v/v	% m/m	ϱ20 (Kg/m³)	d (g/cm³)
71,6	64,10	881,55	0,883137
71,7	64,21	881,30	0,882886
71,8	64,32	881,05	0,882636
71,9	64,43	880,79	0,882375
72,0	64,53	880,54	0,882125
72,1	64,64	880,29	0,881875
72,2	64,75	880,03	0,881614
72,3	64,86	879,78	0,881364
72,4	64,97	879,52	0,881103
72,5	65,08	879,27	0,880853
72,6	65,19	879,01	0,880592
72,7	65,29	878,75	0,880332
72,8	65,40	878,50	0,880081
72,9	65,51	878,24	0,879821
73,0	65,62	877,99	0,879570
73,1	65,73	877,73	0,879310
73,2	65,84	877,47	0,879049
73,3	65,95	877,21	0,878789
73,4	66,06	876,96	0,878539
73,5	66,17	876,70	0,878278
73,6	66,28	876,44	0,878018
73,7	66,39	876,18	0,877757
73,8	66,50	875,92	0,877497
73,9	66,61	875,66	0,877236
74,0	66,72	875,40	0,876976
74,1	66,83	875,14	0,876715
74,2	66,94	874,88	0,876455
74,3	67,05	874,62	0,876194
74,4	67,16	874,36	0,875934
74,5	67,27	874,10	0,875673
74,6	67,38	873,84	0,875413
74,7	67,49	873,58	0,875152
74,8	67,60	873,32	0,874892
74,9	67,71	873,06	0,874632
75,0	67,82	872,79	0,874361
75,1	67,93	872,53	0,874101
75,2	68,04	872,27	0,873840
75,3	68,15	872,00	0,873570
75,4	68,26	871,74	0,873309
75,5	68,38	871,48	0,873049
75,6	68,49	871,21	0,872778
75,7	68,60	870,95	0,872518
75,8	68,71	870,68	0,872247
75,9	68,82	870,42	0,871987
76,0	68,93	870,15	0,871716
76,1	69,04	869,89	0,871456
76,2	69,16	869,62	0,871185
76,3	69,27	869,35	0,870915
76,4	69,38	869,09	0,870654
76,5	69,49	868,82	0,870384
76,6	69,61	868,55	0,870113
76,7	69,72	868,28	0,869843
76,8	69,83	868,02	0,869582
76,9	69,94	867,75	0,869312
77,0	70,06	867,48	0,869041
77,1	70,17	867,21	0,868771
77,2	70,28	866,94	0,868500
77,3	70,39	866,67	0,868230
77,4	70,51	866,40	0,867960
77,5	70,62	866,13	0,867689

This translation does not replace the portuguese version.

% v/v	% m/m	ϱ20 (Kg/m³)	d (g/cm³)
77,6	70,73	865,86	0,867419
77,7	70,85	865,59	0,867148
77,8	70,96	865,32	0,866878
77,9	71,07	865,05	0,866607
78,0	71,19	864,78	0,866337
78,1	71,30	864,50	0,866056
78,2	71,41	864,23	0,865786
78,3	71,53	863,96	0,865515
78,4	71,64	863,69	0,865245
78,5	71,76	863,41	0,864964
78,6	71,87	863,14	0,864694
78,7	71,98	862,86	0,864413
78,8	72,10	862,59	0,864143
78,9	72,21	862,31	0,863862
79,0	72,33	862,04	0,863592
79,1	72,44	861,76	0,863311
79,2	72,56	861,49	0,863041
79,3	72,67	861,21	0,862760
79,4	72,79	860,94	0,862490
79,5	72,90	860,66	0,862209
79,6	73,02	860,38	0,861929
79,7	73,13	860,10	0,861648
79,8	73,25	859,83	0,861378
79,9	73,36	859,55	0,861097
80,0	73,48	859,27	0,860817
80,1	73,60	858,99	0,860536
80,2	73,71	858,71	0,860256
80,3	73,83	858,43	0,859975
80,4	73,94	858,15	0,859695
80,5	74,06	857,87	0,859414
80,6	74,18	857,59	0,859134
80,7	74,29	857,31	0,858853
80,8	74,41	857,03	0,858573
80,9	74,53	856,75	0,858292
81,0	74,64	856,46	0,858002
81,1	74,76	856,18	0,857721
81,2	74,88	855,90	0,857441
81,3	74,99	855,62	0,857160
81,4	75,11	855,33	0,856870
81,5	75,23	855,05	0,856589
81,6	75,34	854,76	0,856299
81,7	75,46	854,48	0,856018
81,8	75,58	854,19	0,855728
81,9	75,70	853,91	0,855447
82,0	75,82	853,62	0,855157
82,1	75,93	853,34	0,854876
82,2	76,05	853,05	0,854585
82,3	76,17	852,76	0,854295
82,4	76,29	852,48	0,854014
82,5	76,41	852,19	0,853724
82,6	76,52	851,90	0,853433
82,7	76,64	851,61	0,853143
82,8	76,76	851,32	0,852852
82,9	76,88	851,03	0,852562
83,0	77,00	850,74	0,852271
83,1	77,12	850,45	0,851981
83,2	77,24	850,16	0,851690
83,3	77,36	849,87	0,851400
83,4	77,48	849,58	0,851109
83,5	77,60	849,29	0,850819

This translation does not replace the portuguese version.

% v/v	% m/m	ϱ20 (Kg/m³)	d (g/cm³)
83,6	77,72	848,99	0,850518
83,7	77,84	848,70	0,850228
83,8	77,96	848,41	0,849937
83,9	78,08	848,11	0,849637
84,0	78,20	847,82	0,849346
84,1	78,32	847,53	0,849056
84,2	78,44	847,23	0,848755
84,3	78,56	846,93	0,848454
84,4	78,68	846,64	0,848164
84,5	78,80	846,34	0,847863
84,6	78,92	846,05	0,847573
84,7	79,04	845,75	0,847272
84,8	79,16	845,45	0,846972
84,9	79,28	845,15	0,846671
85,0	79,40	844,85	0,846371
85,1	79,53	844,55	0,846070
85,2	79,65	844,25	0,845770
85,3	79,77	843,95	0,845469
85,4	79,89	843,65	0,845169
85,5	80,01	843,35	0,844868
85,6	80,14	843,05	0,844567
85,7	80,26	842,75	0,844267
85,8	80,38	842,44	0,843956
85,9	80,50	842,14	0,843656
86,0	80,63	841,84	0,843355
86,1	80,75	841,53	0,843045
86,2	80,87	841,23	0,842744
86,3	81,00	840,92	0,842434
86,4	81,12	840,62	0,842133
86,5	81,24	840,31	0,841823
86,6	81,37	840,00	0,841512
86,7	81,49	839,70	0,841211
86,8	81,61	839,39	0,840901
86,9	81,74	839,08	0,840590
87,0	81,86	838,77	0,840280
87,1	81,99	838,46	0,839969
87,2	82,11	838,15	0,839659
87,3	82,24	837,84	0,839348
87,4	82,36	837,52	0,839028
87,5	82,49	837,21	0,838717
87,6	82,61	836,90	0,838406
87,7	82,74	836,59	0,838096
87,8	82,86	836,27	0,837775
87,9	82,99	835,96	0,837465
88,0	83,11	835,64	0,837144
88,1	83,24	835,32	0,836824
88,2	83,37	835,01	0,836513
88,3	83,49	834,69	0,836192
88,4	83,62	834,37	0,835872
88,5	83,74	834,05	0,835551
88,6	83,87	833,73	0,835231
88,7	84,00	833,41	0,834910
88,8	84,13	833,09	0,834590
88,9	84,25	832,77	0,834269
89,0	84,38	832,45	0,833948
89,1	84,51	832,12	0,833618
89,2	84,64	831,80	0,833297
89,3	84,76	831,48	0,832977
89,4	84,89	831,15	0,832646
89,5	85,02	830,82	0,832315

This translation does not replace the portuguese version.

% v/v	% m/m	ϱ20 (Kg/m³)	d (g/cm³)
89,6	85,15	830,50	0,831995
89,7	85,28	830,17	0,831664
89,8	85,41	829,84	0,831334
89,9	85,54	829,51	0,831003
90,0	85,66	829,18	0,830673
90,1	85,79	828,85	0,830342
90,2	85,92	828,52	0,830011
90,3	86,05	828,19	0,829681
90,4	86,18	827,85	0,829340
90,5	86,31	827,52	0,829010
90,6	86,44	827,18	0,828669
90,7	86,57	826,85	0,828338
90,8	86,71	826,51	0,827998
90,9	86,84	826,17	0,827657
91,0	86,97	825,83	0,827316
91,1	87,10	825,49	0,826976
91,2	87,23	825,15	0,826635
91,3	87,36	824,81	0,826295
91,4	87,49	824,47	0,825954
91,5	87,63	824,13	0,825613
91,6	87,76	823,78	0,825263
91,7	87,90	823,44	0,824922
91,8	88,02	823,09	0,824572
91,9	88,16	822,74	0,824221
92,0	88,29	822,39	0,823870
92,1	88,42	822,04	0,823520
92,2	88,56	821,69	0,823169
92,3	88,69	821,34	0,822818
92,4	88,83	820,99	0,822468
92,5	88,96	820,63	0,822107
92,6	89,10	820,28	0,821757
92,7	89,23	819,92	0,821396
92,8	89,37	819,57	0,821045
92,9	89,50	819,21	0,820685
93,0	89,64	818,85	0,820324
93,1	89,77	818,49	0,819963
93,2	89,91	818,12	0,819593
93,3	90,05	817,76	0,819232
93,4	90,18	817,40	0,818871
93,5	90,32	817,03	0,818501
93,6	90,46	816,66	0,818130
93,7	90,59	816,30	0,817769
93,8	90,73	815,93	0,817399
93,9	90,87	815,55	0,817018
94,0	91,01	815,18	0,816647
94,1	91,15	814,81	0,816277
94,2	91,29	814,43	0,815896
94,3	91,43	814,06	0,815525
94,4	91,56	813,68	0,815145
94,5	91,70	813,30	0,814764
94,6	91,84	812,92	0,814383
94,7	91,98	812,54	0,814003
94,8	92,13	812,15	0,813612
94,9	92,27	811,77	0,813231
95,0	92,41	811,38	0,812840
95,1	92,55	810,99	0,812450
95,2	92,69	810,60	0,812059
95,3	92,83	810,21	0,811668
95,4	92,98	809,82	0,811278
95,5	93,12	809,42	0,810877

This translation does not replace the portuguese version.

% v/v	% m/m	ϱ20 (Kg/m³)	d (g/cm³)
95,6	93,26	809,02	0,810476
95,7	93,41	808,63	0,810086
95,8	93,55	808,23	0,809685
95,9	93,69	807,82	0,809274
96,0	93,84	807,42	0,808873
96,1	93,98	807,01	0,808463
96,2	94,13	806,61	0,808062
96,3	94,27	806,20	0,807651
96,4	94,42	805,78	0,807230
96,5	94,57	805,37	0,806820
96,6	94,71	804,96	0,806409
96,7	94,86	804,54	0,805988
96,8	95,01	804,12	0,805567
96,9	95,16	803,70	0,805147
97,0	95,31	803,27	0,804716
97,1	95,45	802,85	0,804295
97,2	95,60	802,42	0,803864
97,3	95,75	801,99	0,803434
97,4	95,90	801,55	0,802993
97,5	96,05	801,12	0,802562
97,6	96,21	800,68	0,802121
97,7	96,36	800,24	0,801680
97,8	96,51	799,80	0,801240
97,9	96,66	799,35	0,800789
98,0	96,81	798,90	0,800338
98,1	96,97	798,45	0,799887
98,2	97,12	798,00	0,799436
98,3	97,28	797,54	0,798976
98,4	97,43	797,08	0,798515
98,5	97,59	796,62	0,798054
98,6	97,74	796,15	0,797583
98,7	97,90	795,68	0,797112
98,8	98,06	795,21	0,796641
98,9	98,22	794,73	0,796161
99,0	98,38	794,25	0,795680
99,1	98,53	793,77	0,795199
99,2	98,69	793,28	0,794708
99,3	98,86	792,79	0,794217
99,4	99,02	792,30	0,793726
99,5	99,18	791,80	0,793225
99,6	99,34	791,29	0,792714
99,7	99,50	790,79	0,792213
99,8	99,67	790,28	0,791703
99,9	99,83	789,76	0,791182
100,0	100,00	789,24	0,790661

This translation does not replace the portuguese version.

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